

Family Intervention with Caregivers of Children with Dental Needs

Working Title: Family Access to Dentist Study (FADS)

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Tool Revision History:

Version		
Number	Date	Summary of Revisions Made:
.1	4/23/2013	Initial draft
.2	5/23/2013	Major revisions: sections added
.3	5/31/2013	Minor revisions
.4	6/3/2013	Submitted to NIDCR with grant application
.5	2/10/2014	Resubmission to NIDCR with minor revisions: dates of major study events
1.0	2/25/2014	Submitted Original IRB application
1.1	4/8/2014	Resubmitted Original IRB application with revisions; <i>Approved version</i>
2.0	2/24/2015	Submitted to IRB for Continuing Review: revisions to study design and new Washington sites; <i>Approved version</i>
2.1	4/7/15	CROMS staff posted revised version to Rho website
2.2	6/2/2015	NIDCR revised version posted to Rho website. NIDCR used the 2/24/2015 approved IRB protocol to make revisions.
3.0	5/15/2015	Submitted Addendum to IRB for addition of Spanish translations, final dental information (DIG), and Training and Calibration consent and assent forms; <i>Approved version</i>
3.1	6/30/2015	Used 5/15/2015 current approved IRB approved protocol version and integrated NIDCR staff comments from the 2/24/2015 IRB approved Protocol version to post on CROMS website.
3.2	7/06/2015	CROMS staff posted revised protocol version to Rho website
4.0	7/15/2015	Final Version of Protocol after incorporating NIDCR requested changes-Submitted IRB Addendum
4.1	7/25/16	Submitted Addendum to IRB for addition of Bedford City School District in the Ohio site.

STATEMENT OF COMPLIANCE

The study will be conducted in accordance with the International Conference on Harmonisation guidelines for Good Clinical Practice (ICH E6), the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), and the NIDCR Clinical Terms of Award. All personnel involved in the conduct of this study have completed human subjects protection training.

SIGNATURE PAGE

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines.

Principal Investigator and Clinical Site Investigator:

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Date:

Name: Suchitra S. Nelson

Title: Professor

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Date:

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LIST OF ABBREVIATIONS

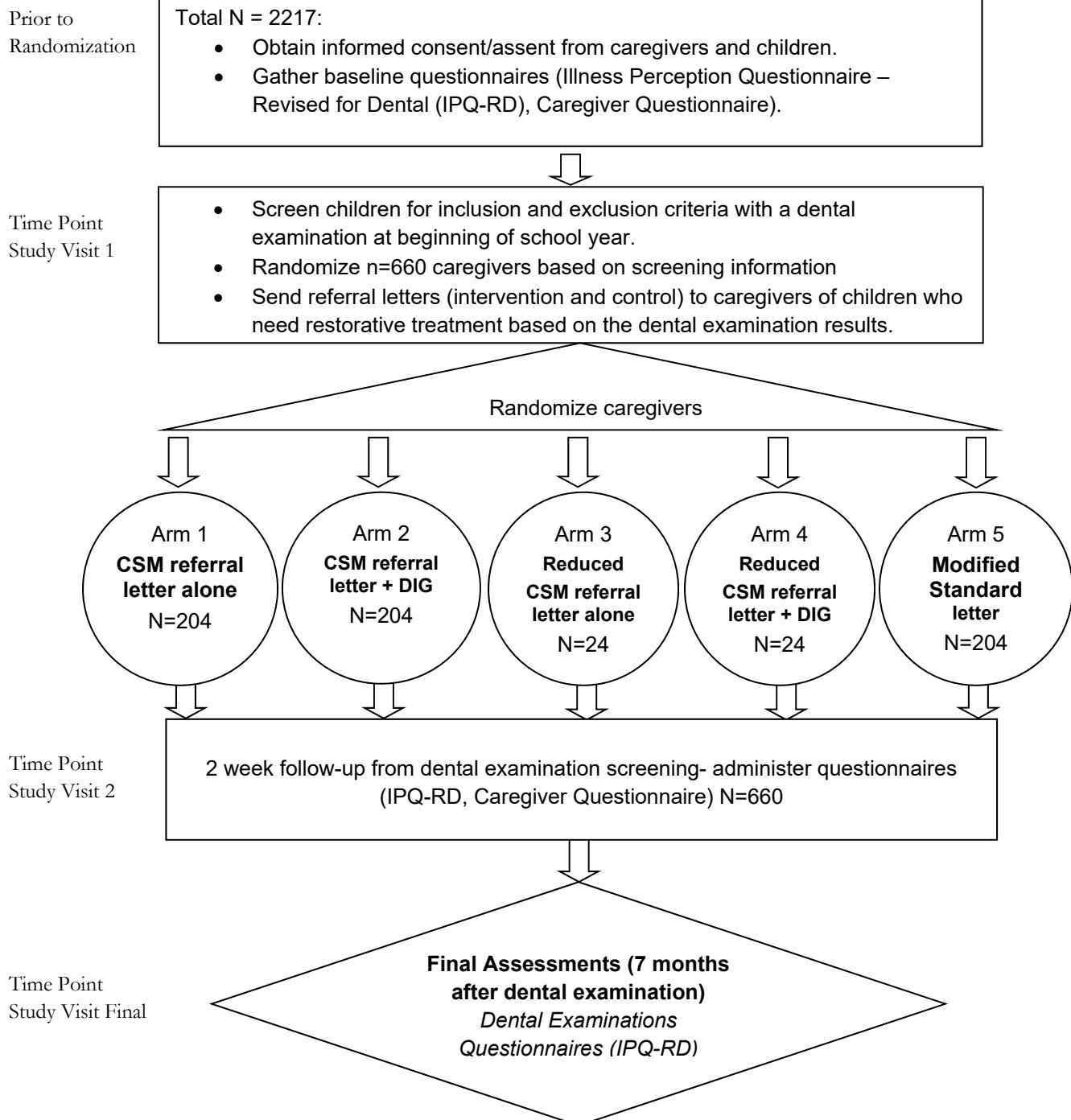
AE	Adverse Event/Adverse Experience
CFR	Code of Federal Regulations
CRF	Case Report Form
DCC	Data Coordinating Center
DHHS	Department of Health and Human Services
DMFS	Decayed, missing, and filled tooth surfaces
DMFT	Decayed, missing, and filled teeth
eCRF	Electronic Case Report Form
FFR	Federal Financial Report
FWA	Federal wide Assurance
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
ICMJE	International Committee of Medical Journal Editors
IRB	Institutional Review Board
MOP	Manual of Procedures
N	Number (typically refers to subjects)
NIDCR	National Institute of Dental and Craniofacial Research, NIH, DHHS
NIH	National Institutes of Health
OCTOM	Office of Clinical Trials Operations and Management, NIDCR, NIH
OHRP	Office for Human Research Protections
PHI	Protected Health Information
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event/Serious Adverse Experience
SOP	Standard Operating Procedure
UP	Unanticipated Problem
US	United States
WHO	World Health Organization

PROTOCOL SUMMARY

Title:	Family Intervention With Caregivers Of Children With Dental Needs
Précis:	The study is a multi-site, double blind, parallel arm, community-based randomized controlled trial (phase III RCT) to evaluate the effectiveness of new referral approaches to increase receipt of dental care among inner-city urban and rural elementary school children who were screened at school and have restorative treatment needs. The study has 5 arms: The experimental intervention is the use of a theoretically driven CSM referral letter alone, the CSM letter plus a Dental Information Guide, a reduced CSM referral letter alone, or a reduced CSM referral letter plus a reduced Dental Information Guide. The control strategy is the use of a modified standard referral letter. All RCT participating K-4 grade children will receive a screening at the beginning of the school year and at the study end point 7 months later to determine if the child received dental care.
Objective	<p>Primary: To evaluate the effectiveness of experimental (new) versus standard referral approaches given to parents/caregivers in increasing receipt of dental care among their children in grades K-4.</p> <p>Secondary: To assess changes in parent/caregiver illness representation/perception and behavioral intention between enrollment (beginning of school year), 2-week and 7-month follow-up (end of school year) to understand the underlying mechanisms of the new vs. standard referral approach that result in receipt of dental care.</p>
Population:	Population information: sample size=660 caregivers to be randomized; children will be both male and female, grades K-4; inner city African Americans (Bedford and E Cleveland, OH) and rural Whites and Hispanics (Cowlitz and Lewis counties, Washington State).
Phase:	III
Number of Sites:	<p>(1) East Cleveland City School District (ECCSD, Cleveland, OH), and Bedford City School District (BCSD, Bedford, OH).</p> <p>(2) Cowlitz County (CCSD, WA), and Lewis County (LCSD, WA).</p>
Description of Intervention:	The experimental intervention is the use of a theoretically driven CSM referral letter alone or the letter plus a dental information guide. The control strategy is the use of a modified standard referral letter.
Study Duration:	10 months
Subject Participation Duration:	1 year

Estimated Time to Complete Enrollment: 3 months

SCHEMATIC OF STUDY DESIGN



1 KEY ROLES AND CONTACT INFORMATION

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Institutions Continued	<p>Cuyahoga County Bedford City School District Central Primary School 799 Washington St. Bedford, OH 44146 Contact: Monique Winston, Principal Telephone: (440) 439-4225</p> <p>Glendale Primary School 400 W. Glendale Ave. Bedford, OH 44146 Contact: Nora Beach, Principal Telephone: (440) 439-4227</p> <p>Carylwood Intermediate School 1387 Caryl Dr. Bedford, OH 44146 Contact: Kenneth Elder, Principal Telephone: (440) 439-4509</p> <p>Columbus Intermediate School 23600 Columbus Rd. Bedford Heights, OH 44146 Contact: Kimberly Sterlek, Principal Telephone: (440) 786-3322</p>
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Institutions Continued	<p>Cuyahoga County East Cleveland City School District Caledonia Elementary School 914 Caledonia Road Cleveland Heights, OH 44112 Contact: Mary Fitzgerald, Principal Telephone: 216-268-6690</p> <p>Chambers Elementary School 14305 Shaw Avenue E. Cleveland, OH 44112 Contact: Crystal Cash, Principal Telephone: 216-268-6640</p> <p>Mayfair Elementary School 13916 Mayfair Road East Cleveland, OH 44112 Contact: Carol Godbold Telephone: 216-268-6651</p> <p>Prospect Elementary School 1843 Stanwood Road East Cleveland, OH 44112 Contact: Charles McCants Telephone: 216-268-6630</p> <p>Superior Elementary School 1865 Garfield Avenue East Cleveland, OH 44112 Contact: Shawna LeSure Telephone: 216-268-6670</p>
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Institutions Continued	<p>Cowlitz County School Districts</p> <p>Kelso School District</p> <p>Catlin Elementary School 404 Long Ave Kelso, WA 98626 Contact: Holly Budge, Principal Telephone: (360) 501-1550</p> <p>Wallace Elementary School 402 Elm Street Kelso, WA 98626 Contact: Jill Steele, Principal Telephone: (360) 501-1650</p> <p>Longview School District</p> <p>Kessler Elementary School 1902 Kessler Blvd Longview, WA 98632 Contact: Debbie Morgan, Principal Telephone: (360) 575-7580</p> <p>St. Helens Elementary School 431 27th Ave. Longview, WA 98632 Contact: Nikki Reese, Principal Telephone: (360) 575-7362</p> <p>Lewis County School Districts</p> <p>Centralia School District</p> <p>Jefferson Lincoln Elementary School 400 W Summa Centralia, WA 98531 Contact: David Eacker, Principal Telephone: (360) 330-7636</p> <p>Winlock School District</p> <p>Winlock Miller Elementary School 405 NW Benton Street Winlock, WA Contact: Boyd Calder, Principal Telephone: (360) 785-3516</p>
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2. INTRODUCTION: BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

2.1 Background Information

The impetus for the proposed behavioral intervention trial comes from a community-based caries prevention trial among low-income minority kindergarten children followed until 2nd grade. During baseline exams, referrals were given for needed restorative and urgent care to the children's caregivers, but on a subsequent dental exam only 19% of the children had received care (Nelson et al. 2012). Standard letters and follow-up phone calls were not effective in improving dental attendance. Recent studies in the U.K. have also concluded that school screening is ineffective in stimulating subsequent dental visits (Milsom et al. 2006a, b). Thus, indications are that caregiver-level engagement or action is necessary to take care of their child's further dental needs without which the benefits of child-level screening or interventions at schools are not realized.

The experimental intervention will be based upon the Common Sense Model of Self-Regulation (CSM: Leventhal et al. 2003) to address parent/caregiver illness perception and navigation of resources to increase receipt of dental care during a 7-month follow-up period for children with restorative dental needs. In this five arm study the new CSM theory-driven referral letter alone or the new CSM referral letter and dental information guide (facts about dental caries, hints for getting dental care, making appointments and Medicaid access, transportation and dentists availability resources) will each be compared to a modified standard referral letter (based on November 2007 guidelines for Oral Health Screening in Ohio Schools) to increase receipt of dental care among inner-city urban African American, and rural Hispanic and White elementary school children.

The literature is clear that most low-income caregivers do not initiate and maintain the self-management strategies necessary for their children's oral health when the children are screened and referred from school. Most see dental diseases as acute, to be responded to only when there is pain or visible decay (Hooley et al. 2012). One approach used in self-management of chronic medical conditions is the Common Sense Model of Self-Regulation (CSM: Leventhal et al. 1997; Leventhal et al. 2003). This approach has never been used in dentistry. The CSM has been used to develop interventions for diabetes (Keogh et al. 2007; McAndrew et al. 2008), asthma (McAndrew et al. 2008), attendance for cardiac rehab (Mosleh et al. 2009), and primary care (Phillips, Leventhal & Leventhal 2012). The CSM proposes that in response to a health threat, people form a cognitive and emotional representation (perception) of their illness that guides coping and action planning, followed by an appraisal of the coping strategy. Five key constructs guiding the illness representation or perception are: Identity, the patient/caregiver labeling of disease and its symptoms; Cause, the individual's perception of the underlying cause of their illness; Consequence, the belief about the impact of the illness physically and socially; Timeline, the personal beliefs about the illness being acute, chronic, or cyclical in nature; and Cure or controllability, the belief whether the illness can be cured or kept under control by the individual or others. The importance of these concepts is that they are readily alterable, as opposed to many other factors in the system. The Illness Perception Questionnaire (IPQ: Weinman et al. 1996; Moss-Morris et al. 2002) has been used to identify these five dimensions of illness representation, together with coherence and emotional representation. A

CSM theory-based letter and information leaflet have been successfully shown to improve cardiac rehab attendance (Mosleh et al. 2009; Sniehotta et al. 2010). Other approaches such as motivational interviewing (MI) have been successful in reducing caries and influence positive behavior change among caregivers (Weinstein et al. 2006) but include multiple counseling sessions that are difficult and expensive when working with low-income populations and are likely not sustainable.

Dental caries is the leading chronic childhood disease (US DHHS 2000). Its prevalence is steadily increasing, with poor and minority children bearing the brunt. Among 2-11 year-olds, 64% of African American children, 60% of Mexican American children, and 50% of White children had untreated tooth decay (Dye et al. 2007). Nevertheless, despite availability of Medicaid, median dental utilization of low-income children is only 33-37% among the states (Hakim et al. 2012; GAO-08-1121, 2008). This trend highlights why so many children require extensive treatment under general anesthesia (Savage et al. 2004). Untreated primary teeth are a strong predictor of future caries indicating the chronicity of the disease (Birkeland et al. 1976; Bader et al. 1986; Van Palenstein et al. 2001; Motohashi et al. 2006). Untreated decay can lead to serious infections and pain, interference with eating/speaking, overuse of EDs, and lost school time (Edmunds et al. 1998). Early preventive care has been shown to reduce later downstream costs (Savage et al. 2004). Poorer oral health-related quality of life was found among preschoolers with ECC (Leal et al. 2012; Martins-Junior et al. 2012; Kramer et al. 2013) and among school children from low-income households (Locker 2007).

Twelve states mandate dental screening of school children. But, the laws do not require tracking and evaluation of children who receive referrals (ASTDD 2008). School screening has also been endorsed by W.H.O. (2003). This is seen as an antidote to prevalent parental views about lack of need for preventive care or treatment of children's decayed but asymptomatic teeth (Milgrom et al. 1998; Riedy et al. 2001; Tickle et al. 2003; Hilton et al. 2007). Recently, Nelson et al. (2012) found 19% dental utilization after school screening, referral, and parental reminders. Studies in the U.K. have also failed to demonstrate the effectiveness of screening (Milsom et al. 2006a,b). A related qualitative study by the same group found the school examination process was acceptable to parents and staff, but the procedure for follow-up was judged inadequate (Tickle et al. 2006). In contrast, other studies with follow-up (Zarod & Lennon 1992; Donaldson & Kinirons 2001; Hebbal & Nagarajappa 2005) reported increases in dental attendance. However, the rate was low even when the care was free; complex factors were involved in the receipt of follow-up care (Hebbal & Nagarajappa 2005). AAPD (2012) policy on school entrance oral examination states such exams are insufficient without follow-up.

2.2 Rationale

First, the new intervention letter addresses two core issues: (a) importance of caries-free primary teeth for protection of permanent teeth and, (b) viewing dental caries as a chronic disease rather than acute or episodic. The current scientific evidence is clear that low-income caregivers do not know the importance of taking care of primary teeth and have the belief that dental caries is present only when the child has pain or symptoms. National surveys also indicate that untreated cavities are disproportionately higher and dental access is lower among Medicaid-eligible children. Therefore, caregivers require an accurate perception of dental caries for them to self-manage their child's cavities and to adopt and maintain healthy behaviors. Hence our rationale for the use of the Common Sense Model of Self-Regulation (CSM) in attempting to change cognitive representation of the 2 core caregiver issues. The text of the intervention letter from the identity construct to timeline

construct is a chain of reasoning aimed at giving information and helping caregivers understand children's dental disease. Second, the new intervention letter also addresses a third core issue, resources to self-manage their child's cavities. For the resources component, the Dental Information Guide (DIG) will address the need for adequate knowledge of resources.

The difficulty that all dental screening programs face, and the one we propose to address, is that few low-income caregivers take their children who have been screened to the dentist for follow-up restorative care.

2.3 Potential Risks and Benefits

2.3.1 Potential Risks

There is no known risk with being in this study. However, some people may feel uncomfortable answering personal questions for research. We will try to make them feel as comfortable as possible and allow them to skip any questions that they choose not to answer. Confidentiality risks may exist if information is misplaced. We will take every precaution to protect participant information and keep it confidential. The child may still receive medical and dental care if the caregiver or the child decides not to be in this study. The dental exam is commonly done in a dental office.

2.3.2 Potential Benefits

The child may benefit if the caregiver learns about his/her tooth problems. If the child has tooth decay, we will give the caregiver a referral to a dentist or dental clinic for dental care. The child may also benefit by learning how to take care of his/her teeth.

3 OBJECTIVES

3.1 Study Objectives

The aim of this study is to evaluate the effectiveness of new referral approaches to increase receipt of dental care among inner-city urban and rural elementary school children who were screened at school and have restorative treatment needs. The primary outcome is the assessment of dental care receipt through dental exams. The secondary outcomes are change in caregiver illness perception, measured through the IPQ-RD, and behavioral intention measured through items in the caregiver questionnaire.

3.2 Study Outcome Measures

Table 3.2.1 shows a summary of the study outcome measures, their sources, and timeline.

3.2.1 Primary Outcome Measures

The primary outcome will be receipt of dental care based on a change determined by clinical examination between baseline and follow-up at study exit (7 months after baseline). Please see MOP Section 5.2 for details of dental exam and criteria.

In addition, other proximal surrogate outcomes from the caregiver questionnaire will also be assessed. These questions include: whether the child visited the dentist after the dental screening, the name of the dentist/dental clinic, whether an appointment was made or not, whether the child completed the needed dental treatment, the number of visits that were made to complete dental treatment, and if they did not complete the treatment the reasons why they did not complete the treatment.

Examiner Training and Calibration: Exams will be conducted in a portable dental chair in the schools by a trained/calibrated examiner. Dr. Hafsteinn Eggertsson will train/calibrate the examiners in the ICDAS protocol in a 4-day central training session. Detailed caries assessment and examiner training, calibration and reproducibility protocols are in the MOP (Section 5.2). Examiners will not utilize dental radiographs. At follow-up, the examiner will not have access to the results of the first examination to avoid detection bias.

3.2.2 Secondary Outcome Measures

The first secondary outcome (mediator) will be change in the overall Illness Perception Questionnaire-Revised for Dental (IPQ-RD), cognitive (identity, consequences, timeline, cause, cure/controllability) representation subscale scores (Weinman et al. 1996; Barrowclough & Lobban 2001; Moss-Morris et al. 2002; Bonetti et al. 2010).

The other secondary outcome (mediator) will be a change in behavioral intention (Luzzi & Spencer, 2008; Ajzen, 1991, 2002). Behavioral intention will be assessed using a caregiver questionnaire and is measured by the summative score of 2 items (e.g., “I want to take my child to the dentist”, and “I plan to take my child to the dentist” on a 5 point scale (Luzzi & Spencer, 2008). The use of these measures will allow us to better understand the mechanisms of action of the intervention based on

our conceptual model. The change in IPQ-RD and behavioral intention scores will be calculated between baseline, two week, and final follow-up. A decrease in IPQ-RD scores (i.e. lower score) indicates better illness representation/perception, while increase in behavioral intention scores indicate a higher intention to take the child to dentist for follow-up care.

Table 3.2.1 Summary of measures, timeline, and source

Variable Type	Measure	Timeline ¹	Source
Exposure (Intervention Study Arms)	<ul style="list-style-type: none"> • CSM referral letter alone • CSM referral letter + DIG • Reduced CSM referral letter alone • Reduced CSM referral letter + DIG • Modified Standard letter 	At randomization	Mosleh et al. 2009 Ohio Department of Health Bureau 2007
Primary Outcome	Dental exams <ul style="list-style-type: none"> • Child's receipt of dental care 	Beginning and end of school year	ICDAS (Pitts 2004)
Secondary Outcomes (Mediators)	IPQ-RD <ul style="list-style-type: none"> • Caregiver illness perception Caregiver Questionnaire <ul style="list-style-type: none"> • Behavioral intention 	Baseline, Two-week, and Exit	Barrowclough et al. 2001 Ajzen 2002; Conner & Armitage 1998
Moderators	Caregiver Questionnaire <ul style="list-style-type: none"> • Caregiver literacy • Caregiver self-efficacy² • Caregiver dental fear • Caregiver perceived stress • Subjective norm² • Dental insurance status Site (urban/rural)	Baseline	Bennett et al. 2003 Finlayson et al. 2005 Humphris et al. 1995 Cohen & Williamson 1988 NHANES IV Ohio, Washington
Confounders	Child's age, race, dental visit Caregiver socio-demographics (age, race, SES, education, marital status)	Baseline	NHANES IV
Subject compliance with Intervention	<ul style="list-style-type: none"> • Whether the referral letter (and DIG) was received (generic code) • Whether the referral letter (and DIG) was read/understood (Postcard) 	Within 2 days after Baseline dental exam	

1. **Baseline:** prior to screening dental exam; **At randomization:** after baseline dental screening exam; **Two-weeks:** Two weeks after randomization; **Exit:** two weeks before end of school year dental exam

2. Caregiver self-efficacy and subjective norms will also be considered as potential **mediators** in the additional mediational analyses, and will be measured at the **Exit** in addition to **Baseline**.

4 STUDY DESIGN

This section describes the model and design of the intervention study. The study will utilize a multi-site, double-blind, parallel arm, community-based randomized trial design (Phase 3).

4.1 Study Participants

Subjects will be parents/caregivers and their children in grades K-4 in one of three Counties: Cuyahoga County (East Cleveland City School District (ECCSD, Cleveland, OH) and Bedford City School District (BCSD, Bedford, OH)); Cowlitz County (CC, WA); and Lewis County (LC, WA); (See Table 4.1.1 below). The study will be offered to all caregivers and their children including those children with special health care needs. Parent/caregivers and children will be enrolled in the study upon signing the consent/assent form and completing the recruitment and contact form. All enrolled children will receive a dental screening at the beginning of the school year. Following the screening, only parent/caregivers whose child has a tooth with an International Caries Detection and Assessment System (ICDAS) active lesion score of 2 or greater will be randomized and continue further participation in the trial. Caregivers with multiple children in K-4 will receive the same intervention assignment.

Table 4.1.1 School District Information

County	School District	Elementary Schools	K-4 Enrollment
Cuyahoga Co.	East Cleveland City SD	Caledonia, Chambers, Mayfair, Superior	889
	Bedford City SD	Central, Glendale, Columbus, Carywood	1274
Cowlitz Co.	Kelso SD.	Catlin, Wallace	1122
	Longview SD.	Kessler, St. Helens	
Lewis Co.	Central SD.	Jefferson Lincoln	586
	Winlock SD.	Winlock Miller	

4.2 Model and Design

Figure 4.2.1 shows the study model for the intervention. The experimental intervention will be based upon the Common Sense Model of Self-Regulation (CSM: Leventhal et al. 2003) to address parent/caregiver illness perception and navigation of resources to increase receipt of dental care during a 7-month follow-up period for children with restorative dental needs. In this five arm study a CSM referral letter alone, a CSM referral letter plus Dental Information Guide (DIG), a reduced CSM referral letter alone, and a reduced CSM referral letter plus DIG will each be compared to a modified standard referral letter (based on November 2007 guidelines for Oral Health Screening in

Ohio Schools) to increase receipt of dental care among inner-city urban African American, and rural Hispanic and White elementary school children.

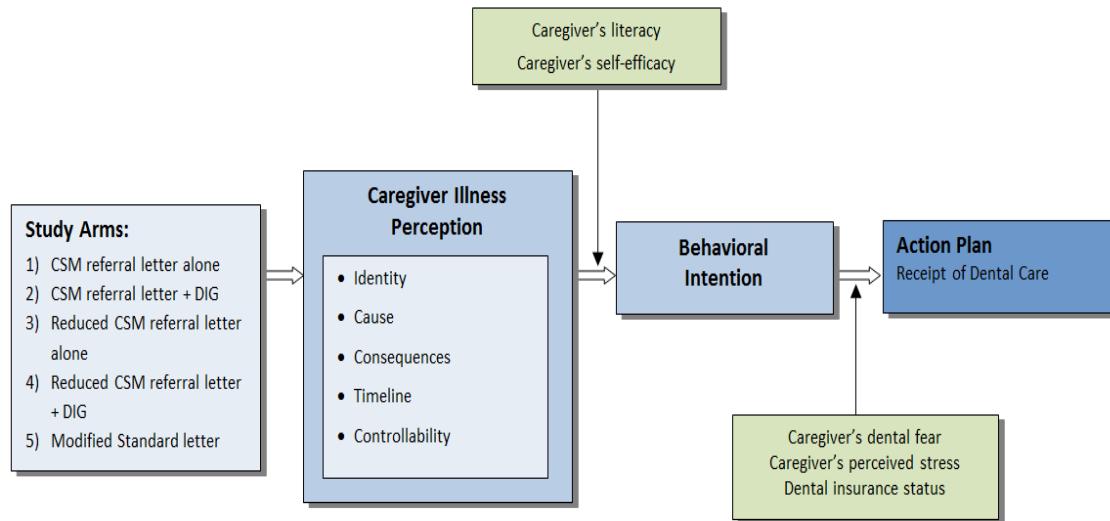


Figure 4.2.1 Conceptual model describing the pathway mechanisms of the proposed new interventions

Figure 4.2.1 illustrates the pathway through which the referral approaches (CSM referral letter alone, CSM referral letter + DIG, reduced CSM referral letter alone, reduced CSM referral letter + DIG, and modified standard letter) are intended to result in action by the caregiver. The child's receipt of care will be mediated by changes in caregiver's illness perception and behavioral intention, which will result from the interventions. The first mediator, caregiver's illness perception is comprised of five constructs such as identity, cause, consequences, timeline, and controllability. The second mediator is caregiver's behavioral intention (Ajzen, 1991), i.e. their motivation or intention for taking their child to the dentist. Intention to initiate an action is also the first step in action planning. The moderating variables in the model are caregiver's literacy, self-efficacy, dental fear, perceived stress, and dental insurance status. Additionally, to test other causal explanations for the effect of the intervention letters on receipt of dental care, measures from the health belief model (HBM: caregiver beliefs and attitudes, self-efficacy) and theory of planned behavior (TPB: subjective norms) theories will also be considered as mediators in this conceptual model. Additional mediational analysis will be conducted to explore alternative causal explanations.

A description of the five study arms is as follows:

Arm 1 (N=204): The first arm is the CSM referral letter alone. The letter text includes the cognitive dimensions of the CSM (identity, cause, consequences, timeline, and controllability). The letter has been tested for readability and clarity with caregivers of K-2 children. The referral letter will be given to the caregivers in their preferred language (English or Spanish).

Arm 2 (N=204): The second arm is the CSM referral letter plus DIG to reinforce/change illness perception, knowledge about dental caries, and resources to seek care. The DIG is a brochure with

illustrations which provides myths and facts about dental caries, hints for getting dental care, making appointments and Medicaid access, transportation and dentist availability resources. While the general information on dental caries is similar for both sites, other resource information on how to seek care and a list of dentists is adapted to the specific site.

Arm 3 (N=24): The third arm is the reduced (removing text corresponding to “timeline”) CSM referral letter alone. The referral letter will be given to the caregivers in their preferred language (English or Spanish). The letter includes the remaining cognitive dimensions of the CSM (identity, cause, consequences, and controllability). While the last line (timeline construct) reinforces the core issues (baby teeth’s impact on adult teeth and the disease’s chronic nature), the text and constructs leading up to the last line is equally important. We think that this final message is fundamental to the intervention letter and this version will allow an estimate of the effect of the “timeline” text itself.

Arm 4 (N=24): The fourth arm is the reduced CSM referral letter plus DIG to reinforce/change illness perception, knowledge about dental caries, and resources to seek care. The reduced DIG is a brochure with illustrations that provides myths and facts about dental caries, hints for getting dental care, making appointments and Medicaid access, transportation and dentist availability resources. As with the reduced letter, text and illustrations related to the “timeline” construct have been removed in the reduced dental information guide. This version will allow for an estimate of the effect of the “timeline” text and illustrations. While the general information on dental caries is similar for both sites, other resource information on how to seek care and a list of dentists is adapted to the specific site.

Arm 5 (N=204): The fifth arm (control) is the modified standard letter (based on November 2007 guidelines for Oral Health Screening in Ohio Schools). This letter is consistent with others used across the country and will be used in both the Ohio and Washington sites.

All letters will be sent home with the child on the day of the screening and mailed to the caregiver’s address within 24 hours. The address will be obtained during recruitment and verified with the school secretary.

A description of the recruitment, enrollment, randomization, and follow-up is below:

Caregivers will be recruited at the beginning of the school year and complete baseline forms (consent form, Illness Perception Questionnaire-Revised for Dental (IPQ-RD) questionnaire, and caregiver questionnaire) prior to dental screening and randomization (Figure 4.2.2). Children in K-4 whose parents have consented/assented will receive a screening exam in early October 2015. Caregivers whose children have no cavities or who have emergent needs will not participate further in the clinical trial. The baseline data from discontinued child and caregiver participants will be used only for baseline descriptive comparisons.

At the same time following screening exams eligible caregivers of children with restorative referrals will be randomized. Caregivers will be followed at 2 time points: 2 weeks after the receipt of the intervention letter and 2 weeks prior to the final (exit) study visit examinations in May 2016 (approximately 7 months after the initial dental exam). At both time points caregivers will complete the IPQ-RD and the caregiver questionnaire. A small sub-sample of 60 caregivers will be randomly

sampled from arms 1, 2 and 5 (20 per arm), to complete the IPQ-RD 1 month after enrollment for reliability purposes. All questionnaires will be mailed to the home address and asked to be returned to the class-room teacher or the outreach staff. Further, outreach staff will ensure that the caregivers received and returned the materials through follow-up calls. The schedule and scripts for the call are contained in the MOP (Table 6.1 and Appendix 6). Children will have a follow-up dental exam in May 2016.

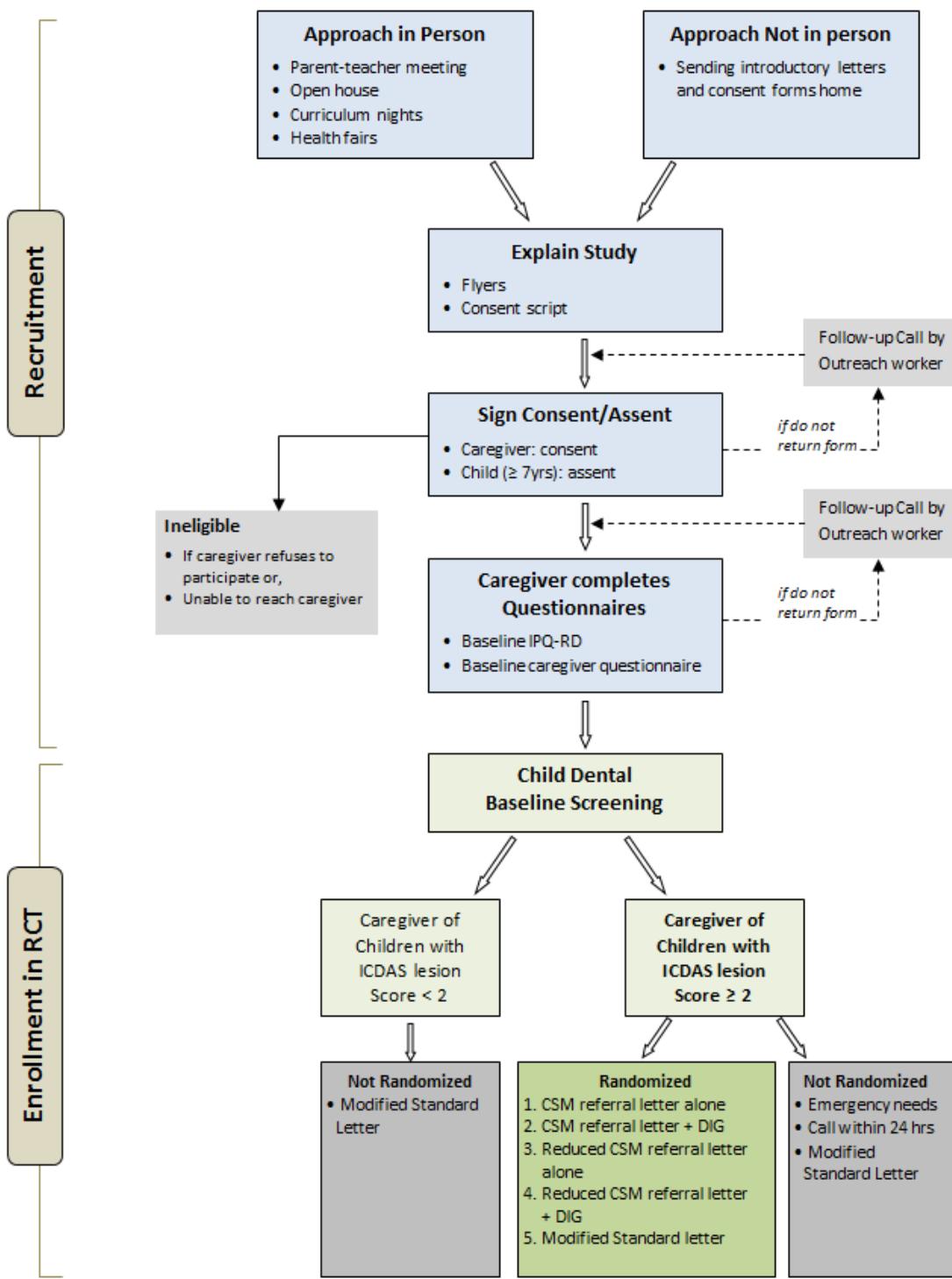


Figure 4.2.2 Flowchart for Recruitment, Enrollment, and Randomization

5 STUDY ENROLLMENT AND WITHDRAWAL

5.1 Subject Inclusion Criteria for Enrollment

Inclusion Criteria: Inclusion criteria for Parents/Caregivers and their children for enrollment:

- Provide signed and dated consent form (also assent form for children 7 and older)
- Willing to comply with all study procedures and be available for the duration of the study
- Male or female child, grades K-4
- Child in good general health as evidenced by parent report (including children with special health care needs). Caregivers will indicate on the Recruitment and Contact Form if their child has any major medical problems or any cognitive or developmental disorders that would preclude them from participating in the dental exam.

Additional Subject Inclusion Criteria for study continuation and randomization:

- Caregivers will be randomized if their child has tooth with an International Caries Detection and Assessment System (ICDAS) active lesion score of ≥ 2 . Caregivers with multiple children in K-4 will receive the same intervention assignment.

5.2 Subject Exclusion Criteria

Exclusion Criteria: Exclusion criteria for Parents/Caregivers:

- Illiterate
- Under 18 years of age

5.3 Strategies for Recruitment and Retention

Subjects will be recruited in Ohio or Washington States and will be volunteers.

Ohio Site: The recruitment follows a 2-stage process (See Section 4.2, Figure 4.2.2): (1) all caregivers of K-4 children enrolled in ECCSD and BCSD will be invited to have their children participate in the dental screening; (2) consented parent/caregivers and assented children will be screened and those who fulfill the inclusion criteria for study continuation and randomization will be randomized. We will follow recruitment strategies that were previously successful working with this minority school-based population (Nelson & Milgrom 2012). The venues for recruitment will include parent-teacher meetings, open house, curriculum nights, health fairs, and at prearranged convenient times during school drop off /pick up of the child. Teacher support will be gained for sending introductory letters and consent forms home to increase recruitment. **Outreach Workers** will be hired from the local community to assist with recruitment at the schools. Candidates will be parent-teacher liaisons who are knowledgeable about the schools and caregivers, and who will foster trust

among caregivers. Based on a previously cited study (Nelson & Milgrom 2012), we expect to recruit 765/889 (86% recruitment rate) from ECCSD. Also based on the previous study, we expect 428/765 recruited children (56% caries rate) will be screened positive for dental caries. Out of the 428, 5% are expected to have acute urgent care needs and be excluded. Further, 10% will be caregivers with multiple children in K-4 and thus will receive the same intervention. A pool of 366 caregivers will be eligible for randomization.

Washington Sites: These sites will use the same recruitment approach as ECCSD. The study intends to recruit 1452/1708 K-4 children (85%). In a recent screening with a similar rural population (Jefferson and Morrow Counties, OR), 85% of families agreed to participate with only a single notice home and no personal contact or follow-up. In an earlier study with a similar rural population, UW investigators recruited 76% of eligible families (Weinstein, Spiekerman & Milgrom 2009). Based on 28% caries rate, we expect that 407/1452 recruited children will be screened positive for untreated caries. 5% of the children who are positive will be excluded because of emergent needs. Further 10% will be caregivers with multiple children. Thus, an available pool of 348 caregivers will be eligible for randomization.

Due to lower than expected enrollment in both the Ohio and Washington sites, we plan a second year of recruitment to include Bedford School District and East Cleveland School District (only KG and perhaps other grades if they did not enroll in the first year). For the Bedford School District, 1274 KG-4th grade children were enrolled during 2015-2016 school year in four elementary schools; 80% Black; 67% economically disadvantaged eligible for free/reduced cost school lunch program. Bedford is quite similar to East Cleveland. Using our experience from the first year of recruitment we expect that out of the 1274 Bedford school children, about 764 will receive baseline screening (60% participation rate). Of 764 children, about 267 caregivers will be randomized (taking into account 30% multiple children and 50% caries rate). Similarly we expect about 50 caregivers will be randomized in East Cleveland. Between Bedford and East Cleveland School Districts, we expect to screen about 950 children in 2016-2017 school year. Of the 950 screened we expect to randomize 317 caregivers. So we can meet our recruitment goal of 258 caregivers that is necessary to complete the study.

5.4 Treatment Assignment Procedures

5.4.1 Randomization Procedures

Sequence Generation: The study Biostatistician will generate the randomization sequence, which will be loaded into REDCap for allocation. REDCap is a secure, web-based application designed to support remote data capture for research studies, providing: 1) an intuitive interface for validated data entry, 2) audit trails for tracking data manipulation and export procedures, 3) automated export procedures for seamless data downloads to common statistical packages, and 4) procedures for importing data from external sources. Caregivers will be randomly assigned to one of the five study arms in the 17:17:2:2:17 ratio; randomization of caregivers will be stratified by their child's grade level and school. The caregivers with multiple children will receive the same treatment based upon the grade level and school of one of their children, selected at random. Permuted blocks will be used to ensure the allocation of treatment assignments within strata as planned. Only the Biostatistician and the Data Manager will be aware of the blocking scheme and the actual assignments.

Allocation Process: Caregivers will be allocated to study arms using the randomization module provided in REDCap. REDCap uses previously-generated randomization sequences to assign records to study arms, and can support up to 14 stratifying variables. Each unique caregiver ID will be linked to one or more unique child IDs in a one-to-many relationship. As each child record is examined, the corresponding caregiver's study arm assignment will be displayed. If no allocation is found, the study staff will be directed to the randomization form to allocate that caregiver to the correct arm. REDCap will assign each caregiver to a specific study arm in accordance with the pre-determined randomization sequence and the stratifying variables. To assist study staff in quickly processing randomizations, stratifying variables (as well as other basic data) will be prepopulated into REDCap by the Project Coordinators, using information gathered prior to the dental screening and randomization process. REDCap is secured using TLS/SSL, enabling study staff to use it from laptops using public or private wireless connections.

5.4.2 Masking Procedures

All personnel who have contact with the child and caregiver will be blinded to participant group assignment except for personnel on the Data & Statistics Team. In order to maintain blinding, the dental examiners will not have access to study arm allocation.

5.5 Subject Withdrawal

5.5.1 Reasons for Withdrawal

Subjects are free to withdraw from participation in the study at any time upon request.

Subjects who drop out (or withdraw) from the study by their own choice will be considered dropouts/withdraws.

An investigator may terminate a study subject's participation in the study if:

- Any medical condition or situation occurs such that continued participation in the study would not be in the best interest of the subject.
- The child transfers out of the school district) that precludes further study participation.

5.5.2 *Participants who are discontinued from the study by one of the study personnel will be considered a discontinuer. Handling of Subject Withdrawals or Subject Discontinuation of Study Intervention*

All reasons for dropout/withdrawal or discontinuation of the study intervention will be documented in the tracking database and reviewed by the study team and **reported to the NIDCR Medical Monitor**. For gathering information on discontinuation, **Outreach Workers** will be contacting subjects at the 2 follow-up time points (2 weeks after initial dental screening and 2 weeks before the last dental screening).

In the event of a subject telling the **Outreach Worker** that he/she is dropping out of the study, the **Outreach Worker** should gather the following information as much as the subject allows.

- Record the reason for dropping out of the study.
- Record any event reported by subjects that the PI determines to be an unanticipated problem.
- Debrief about the intervention.
- Complete the appropriate questionnaire nearest the drop out time point.

If it is determined by study personnel that a participant should be discontinued from the study, the decision to withdraw a participant must be discussed and confirmed by the **PI** and **Clinical Site Investigator**. If both agree that a subject should be withdrawn from the study, the date of withdrawal and reason(s) for withdrawal should be recorded in the tracking database.

5.6 Premature Termination or Suspension of Study

Termination of the study normally would occur at the end of subject accrual and completion of all study procedures. For various reasons a study may terminate prematurely. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to the Principal Investigator (PI) , Medical Monitor, or NIDCR. If the study is prematurely terminated or suspended, the PI will promptly inform the IRB and will provide the reason(s) for the termination or suspension.

Circumstances that may warrant termination include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to subjects.
- Insufficient adherence to protocol requirements.
- Data which are not sufficiently complete and/or evaluable.
- Determination of futility.

6 STUDY INTERVENTION

6.1 Study Behavioral or Social Intervention(s) Description

The new referral intervention letters (Arms 1 to 4) have been based on the CSM theory. Expert input was sought from both CSM experts and other Health Behavior Theory (HBT) experts to assess the consistency of the letter text to the CSM theory. All experts agreed that the new referral text is consistent with the CSM theory. But, the text may not be specific and other theories especially the Health Belief Model (HBM) and Theory of Planned Behavior (TPB) could also be mapping to the letter text. Two ways in which we propose to address this in our study: is to include additional theory-based measures as potential mediators (caregiver beliefs and attitudes, self-efficacy, subjective norms) of the intervention's effects; another way is to report the results of this study where other alternative theories are discussed. The modified standard letter (control) does not map to any HBT constructs.

Arm 1: The intervention is the CSM referral letter alone (English and Spanish; MOP Appendices section 6). The letter text includes the cognitive dimensions of the CSM (identity, cause, timeline, consequences and controllability). Table 6.1.1 gives the letter text and the CSM cognitive constructs that the text maps to. The letter has been tested for readability and clarity with caregivers of K-2 children. The Spanish translation was done by a native Mexican Spanish speaker and back translated by a second individual to ensure comparability. Both versions were written at a 6th grade level or lower. The letter will be sent home with the child on the day of screening and mailed to the caregiver address within 24 hours. School District records include information on the primary language spoken at home. The address will be obtained during recruitment and verified with the school secretary.

Arm 2: The intervention is the CSM referral letter + the dental information guide (DIG; MOP Appendices Section 6) to reinforce/change illness perception, knowledge about dental caries, and resources to seek care. The dental information guide is a brochure with illustrations which provides myths and facts about dental caries, hints for getting dental care, making appointments and Medicaid access, transportation and dentist availability resources. The information guide was pilot-tested and modified based on caregivers and community leaders input. While the general information on dental caries is similar for both sites, other resource information on how to seek care and a list of dentists is adapted to the specific site (see MOP Appendices Section 6 for site-specific DIG). As with the other arms, the letter will be sent home with the child on the day of the screening and mailed to the caregiver's address within 24 hours.

Arm 3: The intervention is the reduced (removing text corresponding to "timeline") CSM referral letter alone (English and Spanish; MOP Appendices Section 6). The letter includes the remaining cognitive dimensions of the CSM (identity, cause, consequences and controllability). While the last line (timeline construct) reinforces the core issues (baby teeth's impact on adult teeth and the disease's chronic nature), the text and constructs leading up to the last line is equally important. We think that this final message is fundamental to the intervention letter and this version will allow an estimate of the effect of the "timeline" text itself. The letter has been tested for readability and clarity with caregivers of K-2 children. The Spanish translation was done by a native Mexican

Spanish speaker and back translated by a second individual to ensure comparability. Both versions were written at a 6th grade level or lower.

Arm 4: The intervention is the reduced CSM referral letter + reduced dental information guide (Reduced DIG; MOP Appendices Section 6) to reinforce/change illness perception, knowledge about dental caries, and resources to seek care. The reduced dental information guide is a brochure with illustrations that provides myths and facts about dental caries, hints for getting dental care, making appointments and Medicaid access, transportation and dentist availability resources. As with the reduced letter, text and illustrations related to the “timeline” construct have been removed in the reduced dental information guide. This version will allow for an estimate of the effect of the “timeline” text and illustrations. While the general information on dental caries is similar for both sites, other resource information on how to seek care and a list of dentists is adapted to the specific site (see MOP Appendices Section 6 for site-specific DIG). The letter will be sent home with the child on the day of the screening and mailed to the caregiver’s address within 24 hours.

Arm 5: The control is the modified standard referral letter (based on November 2007 guidelines for Oral Health Screening in Ohio Schools. MOP Appendices Section 6). This letter is consistent with others used across the country. Both Ohio and Washington sites will use the same standard letter. As with Arms 1, 2, 3 and 4, the letter will be sent home with the child on the day of the screening and mailed to the caregiver’s address within 24 hours.

Table 6.1.1 Text of intervention letter and associated CSM constructs

Intervention letter text	CSM construct
Cavities are the #1 childhood health problem . Children may have cavities even if they do not have pain . Cavities should be treated when found.	Identity
Cavities can be serious in baby teeth. Cavities can affect children’s learning and how they look and feel about themselves .	Consequences
Other health problems may not be under your control. But, you can prevent cavities by taking your child to the dentist at least once a year . Your child will benefit from this greatly.	Controllability
Cavities do not just happen. Bacteria cause cavities. A dentist can clear up the bacteria.	Causes
If cavities are not treated, the bacteria in baby teeth can affect adult teeth .	Timeline

6.2 Administration of Intervention

The referral letter (and dental information guide for Arms 2 and 4) will be sent home with the child on the day of screening and mailed to the caregiver's address within 24 hours. School District records include information on the primary language spoken at home. The address will be obtained during recruitment and verified with the school secretary.

Procedures will be in place to make certain that the referral letters are received. In the R34 pilot study, caregivers preferred to have it mailed. But when the letter was sent home both with the child and also mailed to the caregiver, 75% received the letter either through child or mail or both, while 25% reported they did not receive the letter. To maximize the chance the referral letter and/or information guide are received, a trained Outreach Worker will call the caregiver within 2 days to clarify the receipt: 5 attempts will be made at various times during the day and evening. If the letter was not received, the worker will verify the address and another packet will be sent. The training procedure for the Outreach Workers is in the next section and a more detailed account is in the MOP (Refer to Section 6). In Washington some Outreach workers will be bi-lingual.

6.3 Procedures for Training Interventionists and Monitoring Intervention Fidelity

The **Project Coordinator** in Cleveland and Washington will be responsible for facilitating the caregiver participants' access to the interventions. Given that the nature of the interventions (i.e., referral letters), are structured, the **Project Coordinator** will primarily be responsible for assuring that the letters are sent. **Outreach workers** will be responsible for assuring that letters are received by the caregiver. They will not be personally delivering the intervention information. This makes training and fidelity assessment less complicated. This section generally describes the procedures for training the **Outreach Workers** and monitoring compliance with study procedures (See MOP Section 5.2 for a detailed description).

Project Coordinators will supervise the **Outreach Workers** at their respective sites. Staff training for **Project Coordinators** (Ohio and Washington), and **Outreach Workers** (Ohio only), will be centrally conducted at Case Western Reserve University (CWRU). The Washington **Project Coordinator** will receive training at CWRU and in turn will train the outreach staff at Washington. While the curriculum varies depending on the staff member's role in the project, at a minimum all staff will be trained in the topics of **Human Subject Protection, Good Clinical Practice (GCP), and Protocol training**.

Intervention fidelity ensures that the intervention was conducted as planned, i.e., follows the study protocol. The importance of adhering to the study protocol (e.g., when to send out referral letters, when to make phone calls and following the phone call scripts) will be emphasized during the **Outreach Worker** training as well as following the MOP. One aspect of **Outreach Workers'** duties will require them to make phone calls to caregiver participants confirming receipt of the letters. To ensure that **Outreach Workers** make a similar number of phone calls and provide the same information to each participant the calls will be recorded. The **Project Coordinator** in each respective site will listen to each of the first 10 calls (reminder calls to return the questionnaire). **Outreach Workers** will receive additional training if there are deviations from the script; then.

Then, the first ten (10) of the following remaining type of calls will be recorded and reviewed for each Outreach Worker (confirmation of receipt of referral letters-call #2, and reminders to return completed questionnaires-calls #4 and #6) to assure continued fidelity. Furthermore, all contacts with caregivers will be entered into the tracking database and reviewed to ensure that **Outreach Workers** are following the protocol/MOP.

6.4 Assessment of Subject Compliance with Study Intervention

Procedures will be in place to make certain that the referral letters (and DIG) are received/read/understood. .

The following procedures will maximize the chance that caregivers receive the referral letter (and DIG for Arms 2 and 4):

- Include the same generic code (ex. 1001) at the bottom of all referral letters.
- A trained Outreach worker (OW) will call the caregiver within 48 hours of the dental screening to confirm receipt of the referral letter: 5 attempts will be made at various times during the day and evening.
- When calling to confirm receipt of the referral letter, the Outreach worker will ask the caregiver to read the code at the bottom of the letter.
- If the referral letter was not received, the Outreach worker will verify the caregiver's address and send another one with her/his child or by mail, depending on the caregiver's preference.
- The training procedures for the Outreach workers are described in the next section and a more detailed account can be found in the MOP (Refer to Section 6). In Washington some Outreach workers will be bi-lingual

In addition, to ensure that caregivers read and understood the referral letter, a self-addressed stamped postcard will be enclosed with the referral letter. There will be two questions on the postcard: (a) I have read and understood the letter (yes/no); (b) I understand that my child's dental screening in the school was not a complete dental exam (yes/no). Caregivers will be able to answer question (b) if they read the letter because this sentence is in both the standard and CSM referral letters. Outreach workers will remind caregivers to answer the questions and return the postcard.

7 STUDY SCHEDULE

Refer to Appendix A for the Schedule of Events.

7.1 Screening

Recruitment/Enrollment (Day -56 to -1)

- Recruit potential caregiver participants using an in person approach at several venues including parent-teacher meetings, open house, curriculum nights, health fairs, and at prearranged convenient times during school drop off /pick up of the child. An additional approach is to send home a recruitment packet containing a recruitment flyer and consent forms to increase recruitment.
- Review inclusion/exclusion criteria to determine eligibility (**Refer to Sections 5.1, 5.2**).
- Review the written consent form (**Refer to Section 15.3**) with the potential participant; study staff signs the consent form acknowledging that informed consent was reviewed and caregiver signs acknowledging consent was obtained.
- Obtain (in person or by mail) demographic and contact information and responses to the following questionnaires: Baseline Illness Perception Questionnaire – Revised for Dental (IPQ-RD) and Baseline Caregiver Questionnaire.
- Telephone contact with caregiver if baseline questionnaires are not filled out and returned 2 days after receipt.

7.2 Baseline Dental Screening

Baseline Dental Screening Visit (Visit 1, Day 0-5)

- Obtain assent of child prior to dental screening examination.
- Perform initial child dental screening examination at child's respective elementary school.
- Record results of dental screening examination.
- Randomize caregivers of children with restorative referral outcome on screening to 1 of 5 study arms.
- Send referral letter packets to caregiver with child and by mail.
- Telephone contact with caregivers (within 48 hours of screening examination) to confirm receipt of referral letter packet.

- Resend referral letter packets to caregivers as necessary.
- Follow-up telephone contact with caregivers to confirm receipt of secondary letter.

7.3 Follow-up Visit

Follow-up Visit (Visit 2: 2 weeks after initial dental examination)

- Telephone contact with caregivers (2 days before questionnaires sent) to confirm contact information and let them know the questionnaires will be sent to them.
- Mail 2-week follow-up questionnaires (IPQ-RD and Caregiver) to caregivers.
- Telephone contact with caregivers (7 days after questionnaires are received) to remind them to return questionnaires.
- Additional telephone contacts (1-2 reminders), and then ask for assistance from the teacher.
- Record unanticipated problems or adverse events as reported by subject or observed by investigator.

7.4 Final Study Visit

Final Study Visit (Final Visit: approximately 7 months after initial dental examination)

- Telephone contact with caregivers (2 days before questionnaires sent) to confirm contact information and let them know the questionnaires will be sent to them.
- Mail Final follow-up questionnaires (IPQ-RD and Caregiver) to caregivers.
- Telephone contact with caregivers (7 days after questionnaires are received) to remind them to return questionnaires.
- Perform final child dental screening examination at child's respective elementary school.
- Record results of dental screening examination.
- Record unanticipated problems or adverse events as reported by subject or observed by investigator.

7.5 Withdrawal Visit

Early Withdrawal or Termination Visit (any time investigator withdraws participant or participant terminates from the study)

- In-person contact
- Record any event reported by participants that the PI determines to be an unanticipated problem.
- Debrief about the intervention.
- Obtain responses to the nearest study questionnaires (IPQ-RD, caregiver)

8 STUDY PROCEDURES/EVALUATIONS

The following are the various study procedures and evaluations that will be done during the study:

Administration of questionnaires (IPQ-RD and caregiver questionnaires including demographic information) for caregiver and child information (See Section 3.2, Table 3.2.1; see Appendix C): Caregivers will be asked to complete questionnaires at three time points (baseline prior to screening, 2 weeks after the dental screening examination, and at the end of the school year).

Dental examinations for baseline caries status and primary study outcome: Exams will be performed on the children whose caregivers have consented to their participation. The dental examinations will be done according to the standard caries detection and assessment system termed ICDAS (International Caries Detection and Assessment System). The initial examination (approximately 2 months after the beginning of the school year) will determine a child's need for restorative care which is an inclusion/exclusion criterion for study continuation and randomization. The final examination (approximately 1 month prior to the end of the school year) will be used for the primary study outcome for children enrolled in the RCT.

Administration of the intervention (referral letters) (See Section 6 – Study Intervention): The letter will be sent home with the child and mailed to the caregiver. Confirmation that the letter was received will be obtained through telephone contacts.

9 ASSESSMENT OF SAFETY

9.1 Specification of Safety Parameters

9.1.1 Unanticipated Problems

The Office for Human Research Protections (OHRP) considers unanticipated problems involving risks to subjects or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- related or possibly related to participation in the research (“possibly related” means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Per the definition, only a subset of adverse events would be characterized as unanticipated problems. There are other types of incidents, experiences, and outcomes that are not considered adverse events, but are characterized as unanticipated problems (e.g., breach of confidentiality or other incidents involving social or economic harm).

9.1.2 Adverse Events

An adverse event is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research.

9.1.3 Serious Adverse Events

Serious adverse events (SAEs) are a subset of all adverse events

A serious adverse event (SAE) is one that meets one or more of the following criteria:

- Results in death
- Is life-threatening (places the subject at immediate risk of death from the event as it occurred)
- Results in inpatient hospitalization or prolongation of existing hospitalization
- Results in a persistent or significant disability or incapacity

- Results in a congenital anomaly or birth defect
- An important medical event that may not result in death, be life threatening, or require hospitalization may be considered an SAE when, based upon appropriate medical judgment, the event may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

9.2 Time Period and Frequency for Event Assessment and Follow-Up

Unanticipated problems, AEs and SAEs will be recorded in the data collection system throughout the study.

Given the nature of the intervention (a referral letter and dental information guide), it is unlikely that intervention-related SAEs or AEs will occur. However, throughout the study, if a caregiver or teacher reports an event to any study staff; it will be communicated to the PI immediately. The PI will record all reportable events occurring any time after informed consent is obtained until the last day of study participation. Events will be followed for outcome information until resolution or stabilization.

9.3 Characteristics of an Adverse Event

9.3.1 Relationship to Study Intervention

To assess relationship of an event to study intervention, the following guidelines are used:

1. Related (Possible, Probable, Definite)
 - a. The event is known to occur with the study intervention.
 - b. There is a temporal relationship between the intervention and event onset.
 - c. The event abates when the intervention is discontinued.
 - d. The event reappears upon a re-challenge with the intervention.
2. Not Related (Unlikely, Not Related)
 - a. There is no temporal relationship between the intervention and event onset.
 - b. An alternate etiology has been established.

9.3.2 Expectedness of SAEs

Given the nature of the intervention (a referral letter), it is unlikely that SAEs or AEs will occur which are related to the intervention/study. The NIDCR Medical Monitor and the Study PI will be responsible for determining whether an SAE/AE is expected or unexpected. An adverse event will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the intervention.

9.3.3 Severity of Event

The following scale will be used to grade adverse events:

1. Mild: no intervention required; no impact on activities of daily living (ADL)
2. Moderate: minimal, local, or non-invasive intervention indicated; moderate impact on ADL
3. Severe: significant symptoms requiring invasive intervention; subject seeks medical attention, needs major assistance with ADL

9.4 Reporting Procedures

9.4.1 Unanticipated Problem Reporting to IRBs and NIDCR

Incidents or events that meet the OHRP criteria for unanticipated problems require the creation and completion of an unanticipated problem report form. The following information will be included when reporting an adverse event, or any other incident, experience, or outcome as an unanticipated problem to the University Hospitals Case Medical Center (UHCMC) IRB:

- appropriate identifying information for the research protocol, such as the title, investigator's name, and the IRB project number;
- a detailed description of the adverse event, incident, experience, or outcome;
- an explanation of the basis for determining that the adverse event, incident, experience, or outcome represents an unanticipated problem;
- a description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.

To satisfy the requirement for prompt reporting, unanticipated problems will be reported using the following timeline:

- Unanticipated problems that are serious adverse events will be reported to the UHCMC IRB and to NIDCR (Medical Monitor and Program Official) within 1 week of the study staff/PI becoming aware of the event.
- Any other unanticipated problem will be reported to the UHCMC IRB and to NIDCR (Medical Monitor and Program Official) within 2 weeks of the study staff/PI becoming aware of the problem.

All unanticipated problems will be reported to NIDCR's centralized reporting system via Rho Product Safety:

- Product Safety Fax Line (US): 1-888-746-3293

- Product Safety Email: rho_productsafety@rhoworld.com

General questions about SAE reporting will be directed to the Rho Product Safety Help Line (available 8:00AM – 5:00PM Eastern Time):

- US: 1-888-746-7231

9.4.2 Serious Adverse Event Reporting to NIDCR

Any AE meeting the specified Serious Adverse Event criteria will be submitted (by fax or email) on an SAE form to NIDCR's centralized safety system via Rho Product Safety. Once submitted, Rho Product Safety will send a confirmation email to the investigator within 1 business day. The investigator will contact Rho Product Safety if this confirmation is not received. This process applies to both initial and follow-up SAE reports.

SAE Reporting Contact Information:

- Product Safety Fax Line (US): 1-888-746-3293
- Product Safety Email: rho_productsafety@rhoworld.com

General questions about SAE reporting will be directed to the Rho Product Safety Help Line (available 8:00AM – 5:00PM Eastern Time):

- US: 1-888-746-7231

The PI will complete a Serious Adverse Event Form and submit via fax or email within the following timelines:

- All deaths and immediately life-threatening events, whether related or unrelated, will be recorded on the Serious Adverse Event Form and submitted to Product Safety within 24 hours of site awareness.
- Serious adverse events other than death and immediately life-threatening events, regardless of relationship, will be reported by fax within 72 hours of site awareness.

All SAEs will be followed until resolution or stabilization.

9.5 Halting Rules

Discontinuation of the study will be determined by standard NIH policies and procedures. Given that the study procedures are deemed “minimal risk”, it is unlikely that the trial would need to be discontinued early because of concern for human subjects. The PI and NIDCR will share responsibility in monitoring progress on this study, including progress toward meeting the recruitment and retention goals, data quality and integrity, and protections of human subjects.

10 STUDY OVERSIGHT

In addition to the PI's responsibility for oversight, study oversight will be under the direction of the NIDCR Medical Monitor. The PI will submit a report every 6 months to the NIDCR Medical Monitor for review. This report will include data regarding enrollment and retention, unanticipated problems and protocol deviations, disposition of biospecimens, outcome measures, quality management findings and other relevant parameters. If necessary, additional steps may be taken to ensure data integrity and protocol compliance.

11 CLINICAL SITE MONITORING

Clinical site monitoring is conducted to ensure that the rights of human subjects are protected, that the study is implemented in accordance with the protocol and/or other operating procedures, and that the quality and integrity of study data and data collection methods are maintained. Monitoring for this study will be performed by NIDCR's Clinical Research Operations and Management Support (CROMS) contractor. The monitor will evaluate study processes and documentation based on NIDCR standards and the International Conference on Harmonisation (ICH), E6: Good Clinical Practice guidelines (GCP).

Details of clinical site monitoring will be documented in a Clinical Monitoring Plan (CMP) developed by the CROMS contractor, in collaboration with the NIDCR Office of Clinical Trials and Operations Management (OCTOM) and the NIDCR Program Official. The CMP will specify the frequency of monitoring, monitoring procedures, the level of clinical site monitoring activities (e.g., the percentage of subject data to be reviewed), and the distribution of monitoring reports. Some monitoring activities may be performed remotely, while others will take place at the study site(s). Staff from the CROMS contractor will conduct monitoring activities and provide reports of the findings and associated action items in accordance with the details described in the CMP. Documentation of monitoring activities and findings will be provided to the site study team, the study PIs, OCTOM, and the NIDCR. The NIDCR reserves the right to conduct independent audits as necessary.

12 STATISTICAL CONSIDERATIONS

12.1 Study Hypotheses

We hypothesize that the CSM-based interventions will increase receipt of dental care compared to the modified standard referral letter.

12.2 Sample Size Considerations

The primary aims are to compare dental care receipt among the five intervention groups, overall and separately for each study site (Ohio and Washington).

The five intervention groups are:

Arm 1: CSM referral letter alone (N=204)

Arm 2: CSM referral letter + DIG (N=204)

Arm 3: Reduced CSM referral letter alone (N=24)

Arm 4: Reduced CSM referral letter + DIG (N=24)

Arm 5: Modified Standard letter (N=204)

The utilization will be defined as evidence of dental care through restorations or extractions at the final study visit exam that was previously not found during the baseline exam. All changes will be recorded on a tooth level using ICDAS criteria and then dichotomized at the caregiver level as having obtained or not obtained dental care for their child/children.

There are three treatment comparisons to assess the overall CSM referral letter and DIG: CSM referral letter alone versus standard letter (Arm 1 vs Arm 5), CSM referral letter plus DIG versus standard letter (Arm 2 vs Arm 5), and CSM referral letter alone versus CSM referral letter plus DIG (Arm 1 vs Arm 2). As described below we address the issue of multiple testing, both multiple comparisons and multiple sites, using a gatekeeper approach. By specifying a sequence of tests, this approach will allow for the use of a nominal 0.05 alpha level for each test while maintaining a 0.05 family-wise alpha level for the six tests (three at each study site).

An additional comparison will be conducted to assess the effect of the targeted component (e.g., the ‘timeline’ text): CSM referral letter with and without DIG versus reduced CSM referral letter with and without DIG (Arm 1, 2 vs Arm 3, 4).

The sample size was calculated with the following assumptions for the overall effect of the intervention letter: 19% utilization rate for standard letter (Nelson et al. 2012), 37% rate for CSM referral letter alone (based on Medicaid utilization among children: GAO-08-1121, 2008), 57% rate for CSM referral letter + DIG (based on 57% who reported that they took their child to the dentist or had an appointment after receiving the CSM referral letter + DIG in the R34 study). Then, using a two-sided test for equal proportions (namely, a Z test with pooled variance), we find that a sample size of 102 per intervention group per site (thus, 306 subjects per site) will provide 80% power to detect rate differences of 19% versus 37% (as expected for Arm 5 vs Arm 1) or 37% versus 57% (as expected for Arm 1 vs Arm 2) for each site, and 98% power for each of these comparisons using the

combined sample. As siblings (with the same caregiver) may be included in the study, a conservative approach will be to consider the required sample sizes as referring to the number of caregivers. Somewhat greater power will be expected if within-caregiver correlation is less than 1.

For the Ohio site with a total of 889 potential children, we expect 86% to participate (Nelson & Milgrom 2012), with 56% receiving a referral and 5% excluded for emergent needs. From previous Dr. Nelson's study in ECCSD elementary schools we expect 10% of caregivers to have multiple (usually two) children. Thus, an estimated total of 366 caregivers will be available for randomization to the five groups. For the Washington sites, with a total of 1704 potential children, we expect 85% participation (based on 2013 screenings in both districts), with 28% receiving a referral, 5% exclusions for emergent needs, and a 10% reduction in the corresponding number of caregivers due to inclusion of siblings. A total of 347 caregivers will be available for randomization. Even with 5% out of school transfers, the available sample will be adequate for testing the proposed hypothesis. Thus, we expect to randomize 330 caregivers/site to the five study arms to account for any drop-outs at randomization and maintain the required power for the trial.

With regard to our secondary endpoint, the overall IPQ-RD score, we note that our expected sample size will provide for each site 80% power to detect an 10 point decrease in the mean score (e.g., from an expected mean of 127 for the standard letter to 117 for the CSM referral letter) assuming a common standard deviation of 27 (estimated from previous data). A decrease in IPQ-RD scores indicates better illness representation/perception of caregiver. Since the IPQ-RD has never been utilized previously, we refer to a popular rule of thumb (Cohen, 1988) which considers the above standardized effect size of 0.37 (10/27) as a medium, and thus plausible, effect size.

The statistical test of the effect of the targeted component (timeline) will involve a comparison of 408 (Arm 1, 2) versus 48 (Arm 3, 4) subjects. This test may have low power, particularly if the effect of the targeted text is not large. However, including these arms will allow this effect to be estimated and thus provide some idea of its relative contribution in this exploratory analysis, as well as allow us to detect a large effect (if the component is responsible for a large proportion of the CSM referral letter effect).

12.3 Planned Interim Analysis

No interim analysis is planned.

12.4 Final Analysis Plan

Primary Statistical Analysis: Descriptive statistics will include frequencies (categorical variables) and means (continuous variables) of baseline covariates among the five intervention groups. Chi-square tests (for categorical variables) and t-tests (for continuous variables) will be performed to test for group differences (by site and overall). In our primary analysis, we will fit multivariate generalized linear (specifically, logistic regression) models with dental care receipt as the (binary) outcome and the child as the unit of analysis (as receipt of dental care will be determined for each child). A generalized estimating equations (GEE) approach (with an exchangeable working correlation structure) will be used to allow for correlations among multiple children for a given caregiver. Separate models will be fit for each site as well as overall. The models will include two indicator variables representing the three interventions. Each model will include an a priori selected set of

baseline variables (listed below) and, for the overall model, an indicator variable for site. Secondarily, we will fit a model with a site by intervention group interaction, and the latter will be tested to formally assess possible intervention effect heterogeneity over sites.

We will also consider working correlation structures (e.g., alternating logistic regressions) that allow for second-level clusters, namely schools (within which the first-level cluster, caregiver, is nested). We will determine final models based on the quasi-likelihood information criterion (QIC). Intervention (and other covariate) effects will be tested using generalized score statistics.

Given the parameter estimates from the above models, we use a model-based standardization approach (Albert et al. 2011) to estimate relative risks (i.e., the ratio of the probabilities of dental usage for a given pair of interventions). A bootstrap approach will be used to obtain a 95% confidence interval for each relative risk. Significance will be determined using a gatekeeper approach to hypothesis testing. Specifically, we will first test for a difference in dental care receipt rates for S vs CSM+DIG (at the 0.05 nominal alpha level). If (and only if) this test is significant, we will proceed to test S vs. CSM alone and CSM vs CSM+DIG (both at the 0.05 nominal alpha level). We will use a similar approach for testing for each site. We will start by testing (for a given treatment comparison) an overall effect (stratifying over sites) at the 0.05 nominal alpha level. If (and only if) this is significant, we will then test (for the same treatment comparison) the effect within each site (at the 0.05 nominal alpha level). A 0.05 family-wise error level is attained in this approach assuming that a (true) effect for S vs. CSM+DIG implies a (true) effect for either S vs. CSM or CSM vs. CSM+DIG (or both), and that an overall effect implies an effect in one or both sites (which is logically the case).

To test the effect of the targeted component (timeline), we will fit the same multivariate generalized linear (specifically, logistic regression) models mentioned above with additional indicator representing reduced text.

Adjustment for Baseline Characteristics: Estimated intervention effects (described above) will be adjusted for the following baseline socio-demographic variables: child's age, race, and caregiver SES, education, and marital status.

Model Assumptions: We will assume that the probabilities of dental care receipt follow the selected logistic regression model (controlling for covariates) mentioned above. We assume that the outcomes for different caregivers (or different schools if a correlation structure for two cluster levels is used) are independent.

Analysis of Secondary Outcomes (Questionnaire data): Summary statistics (including means and standard errors) for questionnaire responses for both the IPQ-RD and behavioral intention items within the caregiver questionnaire will be calculated by site and intervention group. This will be done for the overall questionnaire (IPQ-RD and behavioral intention), for each of the five IPQ-RD cognitive constructs, and the two behavioral intention questions. Analyses will be done by site and overall (controlling for site). A summary measure approach, based on the mean questionnaire response, will be used to compare questionnaire outcomes across intervention groups, for the overall questionnaire and by construct. Specifically, for each construct (or overall) a linear regression model will be used with the mean response as the dependent variable, and intervention group

indicators and selected baseline (control) covariates as independent variables. Inferences (that is, p-values and confidence intervals) will be performed assuming summary measures are normally distributed. This assumption will be tested using the Shapiro-Wilk statistic and if violated a suitable transformation of the summary measure used or a nonparametric approach (e.g., using ranks of the summary measures) conducted.

In the event of missing questionnaire responses, we will first assess whether the data are missing completely at random (MCAR), that is, whether missingness for a given item is dependent only on participant baseline characteristics and not further on any other item responses. This will be done using a generalized estimating equations (GEE) approach, that is, by fitting a multivariate generalized linear (e.g., logistic regression) model to missing data indicators for each item, including as explanatory variables selected baseline covariates and other item responses, and testing for an effect of the latter.

If the MCAR assumption is deemed reasonable (no significant effect found), we will conduct the above regression analyses with mean outcomes based on available data. A weighted analysis (that is, regression with the use of the weighted least squares criterion) will be conducted to adjust for differential missingness (thus, non-homogeneous summary measure variances) among participants. If the MCAR assumption is found to be violated we will use a multiple imputation approach (in conjunction with the summary measure approach) using a suitable imputation model (i.e., using other item responses). For each construct (or overall) we will perform an F-test for a difference in the mean summary measure among the three intervention groups, and obtain nominal 95% confidence intervals for pairwise mean differences. If necessary, we will include a random effect for school.

In addition to assessing the overall effects of the interventions, we will investigate the mechanisms (or paths) through which interventions impact dental care receipt. As represented in Figure 1, we hypothesize that a significant portion of the intervention effect will occur via a three-link path: intervention will affect caregiver illness representation which will in turn affect behavioral intention which will in turn affect dental care receipt. Initially, we will consider an overall average score for caregiver illness representation and for behavioral intention. We have previously developed a generalized causal mediation analysis methodology (Albert and Nelson, 2011) which we can use to estimate and test this specific path effect. It is possible that other paths may also be involved – namely, a direct path (possibly involving unidentified mediators) from intervention to dental care receipt, and paths through either caregiver illness representation or behavioral intention alone. We will therefore decompose the overall effect, and estimate the contribution of each of the four possible paths. For each (broadly defined) mediator, we may be interested in examining multiple components (e.g., summary scores or factors representing specific constructs for caregiver illness representation, and the two questions of behavioral intention). We may thus handle each mediator in our model as multidimensional (that is, a vector of latent or observed variables). In addition, we will consider a further refinement of the model, and decomposition of the intervention effect, by allowing separate paths through the individual components of each mediator. The 2-week measurement time for the mediators reflects the hypothesized time of maximum impact of the intervention. However, we will make use of the 7-month measurements of the mediators to assess any changes in the effect of the intervention over time, as well as the relationship between the mediators (at alternative times) and dental care receipt.

As a supplementary analysis, we will use measurements of self-efficacy (from the Caregiver Questionnaire given at 2 weeks and exit) to test the Health Belief Model as an alternative explanation for the effectiveness of the experimental intervention. Specifically, the mediation effect through self-efficacy will be assessed using a similar model and approach as described above. The relative contribution of the multiple hypothesized mediators will also be examined by including them together in a multiple mediator model.

13 SOURCE DOCUMENTS AND ACCESS TO SOURCE DATA/DOCUMENTS

Each participating site will maintain appropriate research records for this study, in compliance with ICH E6, Section 4.9 and regulatory and institutional requirements for the protection of confidentiality of subjects. Each site will permit authorized representatives of NIDCR and regulatory agencies to examine (and when required by applicable law, to copy) research records for the purposes of quality assurance reviews, audits, and evaluation of the study safety, progress and data validity.

Each intervention site (CWRU, UW) will maintain appropriate research records for this study. All records with identifiable information will be kept in secured locked storage units. Only local (e.g., **Outreach Workers**), and CWRU, UW study personnel, the NIDCR Medical Monitor, and NIDCR staff appointed to the trial will have access to the records. Access by the NIDCR Medical Monitor and NIDCR staff is for the purposes of quality assurance reviews, audits, and evaluation of the study safety and progress.

Specific original documents and data records include, but are not limited to:

- Consent chart with all participant-identifying information: Includes signed consent/assent forms, consent documentation, caregiver recruitment and contact form, unanticipated problem or adverse event report forms, and reimbursement logs. These documents will contain the participant's name and other confidential information (e.g. names of child/children and other family members).
- Case Report Forms (CRF): e.g., child baseline and final follow-up ICDAS dental caries assessment form; child baseline and final follow-up dental screening form; Caregiver and IPQ-RD baseline, 2-week follow-up, and final follow-up questionnaires (paper-based and electronic)
- Non-CRF forms: e.g., progress notes checklist (paper-based)
- Recorded audio tapes of Outreach Workers' phone calls (electronic; audio tapes are kept for only 8 weeks)
- Tracking logs
- Memoranda (paper-based)

14 QUALITY CONTROL AND QUALITY ASSURANCE

14.1 Definitions

Quality Assurance (QA)

The process to ensure the quality of the intervention meets the study design expectations.

Quality Control (QC)

A set of routine technical activities to measure and control the quality of the intervention and accuracy of data acquisition as the intervention is being implemented.

14.2 Study Intervention and Study Questionnaires

Quality Assurance Procedures

The **Outreach Workers and study staff**, who will facilitate the receipt of intervention letters and access to the study questionnaires, will attend a 2-day in person training on the conduct of the study protocol and logistics (See MOP Section 5). In-class training will incorporate the topics of human subject protection, Good Clinical Practice (GCP), and the study protocol. A segment of the training will emphasize how data management procedures promote high-quality data collection and reduce threats to fidelity. Focus will be placed on following the procedures that have been outlined in the protocol, principles of data management, and forms administration procedures. All types of documentation will be discussed including forms filled out by participants and study forms completed by staff. For each, the purpose, instructions for completion and procedures to maintain accuracy will be addressed. As part of tracking and managing study records, staff members will learn how to document activities that occur with subjects, update study documentation, and use the tracking logs. As part of the training, the study staff will be certified in the topics presented to ensure their comprehension of the expectations.

Fidelity of the **Outreach Workers'** telephone contacts with caregivers will be assessed throughout the study to ensure that they have not provided additional information to the childrens' caregivers that might influence the outcome. (Refer to MOP Section 5).

For reliability purposes and to further assess the stability of the IPQ-RD presumably after visits to the dentists (between 2 and 4 weeks), we will randomly select a sub-sample of 60 caregivers (20 each in arms 1, 2, and 4) to respond to the IRQ-RD after 4 weeks.

Quality Control Procedures

The first ten (10) **Outreach Workers** telephone contacts (reminder calls to return the questionnaires) will be audio recorded in digital media and reviewed. Then, the first ten (10) of the following remaining type of call will be recorded and reviewed for each Outreach Worker (confirmation of receipt of referral letters-calls #2, and reminders to return completed questionnaires-calls #4 and #6). At the beginning of the study, the **Project Coordinators** will review the first ten telephone contacts to ensure fidelity of the calls and accuracy of data recording.

Outreach Workers will be provided with feedback on their performance and conduct including but not limited to these specific areas; adherence to telephone script, adherence to protocol/MOP, adherence to good clinical practice. **Outreach Workers** with a telephone contact with less than acceptable quality will receive a private training session focused on problematic areas. This QC activity will take place until the first ten sessions have been completed after implementation of the study intervention. This will ensure that any weaknesses in study protocol will be addressed early.

All data entry of study forms and questionnaires will be the responsibility of the **Project Coordinators** at each site (CWRU and UW) with overall monitoring responsibility by the Data and Statistics Team at CWRU. **Outreach Workers** will send completed forms/questionnaires to the CWRU/UW for data entry where they will be stored in secured/locked file cabinets. Each form and questionnaire will be entered and verified by two separate individuals. Any field that is unclear will be clarified with the **Outreach Worker** or caregiver who completed the document. After each study visit, all study forms and questionnaires collected and entered into the database will be merged and cross checked for inconsistencies and range and assessed for missing data. Any inconsistencies, outliers, or missing data observed will be compared to the paper document and appropriate corrective actions carried out.

15 ETHICS/PROTECTION OF HUMAN SUBJECTS

15.1 Ethical Standard

The investigators will ensure that this study is conducted in full conformity with the principles set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, as drafted by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (April 18, 1979) and codified in 45 CFR Part 46 and/or the ICH E6; 62 Federal Regulations 25691 (1997).

15.2 Institutional Review Board

University Hospitals Case Medical Center Institutional Review Board will serve as the IRB of record, with University of Washington IRB being the reliant IRB. The University of Washington study sites will utilize the University Hospitals Case Medical Center IRB approved consent and assent forms. The protocol, informed consent form(s), recruitment materials, and all subject materials will be submitted to the University Hospitals Case Medical Center (FWA#: 00004428) IRB for review and approval. Approval of both the protocol and the consent form must be obtained before any subject is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented in the study.

15.3 Informed Consent/Assent Process

Informed consent is a process that is initiated prior to the individual agreeing to participate in the study and continues throughout study participation. Extensive discussion of risks and possible benefits of study participation will be provided to subjects and their families, if applicable. A consent form describing in detail the study procedures and risks will be given to the subject. Consent forms will be IRB-approved, and the subject is required to read and review the document or have the document read to him or her. The investigator or designee will explain the research study to the subject and answer any questions that may arise. The subject will sign the informed consent document prior to any study-related assessments or procedures. Subjects will be given the opportunity to discuss the study with their surrogates or think about it prior to agreeing to participate. They may withdraw consent at any time throughout the course of the study. A copy of the signed informed consent document will be given to subjects for their records. The rights and welfare of the subjects will be protected by emphasizing to them that the quality of their clinical care will not be adversely affected if they decline to participate in this study. The consent process will be documented in the research record.

Informed consent is acquired once at the start of the academic school year from the parent(s)/caregiver(s) who choose to participate in the study. The informed consent process begins prior to the parent(s)/caregiver(s) agreeing to be in the study and continues for the entire time he/she is in the study. Informed consent must be acquired in order to allow K-4th grade children to undergo the screening exam, and prior to the parent/caregiver's completion of the baseline IPQ-RD and Parent Questionnaire and randomization into the trial. Additionally, assent will be obtained from children in 3rd and 4th grades who are 7 years of age or older. Site-specific written informed consent and assent will be obtained from all study participants using only the stamped approved

forms (See Appendix B). Consent/Accent from the participant will be obtained by the project staff prior to enrollment and the participant can withdraw consent at any time during the study. The project staff will briefly explain the research study and answer any questions. The project staff will discuss the possible benefits and risks related to taking part in the study. The rights and welfare of the children will be protected by emphasizing to them that the quality of their care will not be adversely affected in the event that the parent(s)/caregiver(s) do not want to be contacted to participate in the clinical trial phase of the project. If the parent(s)/caregiver(s) are unsure about participating he/she may take the study information and flyer home to discuss with his/her family or to think about it prior to agreeing. Once informed consent is obtained via the University Hospitals Case Medical Center consent form, consent continues for the entire time the parent/guardian is in the study. The study participants will receive a copy of the signed and dated consent/assent document. The study personnel will maintain the documentation of consent/assent in the consent documentation form (see MOP; Appendices Section 3).

15.4 Subject Confidentiality

Subject confidentiality is strictly held in trust by the PI and Clinical Site Investigator, their staff, representatives for University Hospitals Case Medical Center Institutional Review Board, and the representatives of the study sponsor (NIDCR). This confidentiality is extended to cover mental status in addition to the clinical information relating to participating subjects.

The study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

The study monitor or other authorized representatives of the sponsor may inspect all documents and records required to be maintained by the investigator. The intervention site will permit access to such records.

16 DATA HANDLING AND RECORD KEEPING

The investigators are responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data. The investigators will maintain adequate case histories of study subjects, including accurate case report forms (CRFs), and source documentation. (See MOP Section 10)

16.1 Data Management Responsibilities

Data collection and accurate documentation are the responsibility of the **Outreach Workers** and **Project Coordinators** under the supervision of the PI and Clinical Site Investigator. All source documents must be reviewed by the study team and data entry staff, who will ensure that they are accurate and complete. Unanticipated problems and adverse events must be reviewed by the PI.

16.2 Data Capture Methods

Data for this study are captured using examinations, forms, questionnaires, and audio recordings. Study data will be collected and stored using the REDCap platform. REDCap is a secure, web-based application designed to support remote data capture for research studies, providing: 1) an intuitive interface for validated data entry, 2) audit trails for tracking data manipulation and export procedures, 3) automated export procedures for seamless data downloads to common statistical packages, and 4) procedures for importing data from external sources.

Study forms will be completed by study personnel on paper, and subsequently entered into REDCap by study staff. Because randomization is contingent upon the computer, no paper randomization forms will be completed. Paper forms will be securely stored in a locked file cabinet at both sites when they are not in use. Completed paper forms will be transferred between sites via courier or other secure document service. Similarly, questionnaires used in the study (IPQ-RD, Caregiver Questionnaire) will be completed by subjects on paper sheets and returned to Outreach Workers in each school. Study staff will enter the information into the secure web-based REDCap system. Recorded audios will be stored in secured/locked cabinets in one of the **Project Coordinators'** offices.

16.3 Types of Data

Data for this study will include: (1) dental examination data; and (2) study questionnaires. Additionally, audio tapes will be used for fidelity monitoring. Form revisions should be minimal, however, should they occur, changes will be submitted to the study team for updating and dissemination to **Outreach Workers**.

16.4 Schedule and Content of Reports

Dental examination and study questionnaire data will be reviewed for accuracy and completeness after each study visit. The **Outreach Workers** will review the questionnaires after the participants have completed them, and the Project Coordinators and the **Data and Statistics Team** will do a final review after the documents have been transmitted. An annual report (or as requested by the

NIDCR Medical Monitor or **NIDCR Program Official**) will also be generated for sharing progress of the study.

The **Data & Statistics Team** will generate regular reports showing enrollment and potential data anomalies, which will be sent to **PIs, Project Coordinators**, and other relevant study staff. The **Data Manager** will work with the **PIs** at each site to resolve any data anomalies that arise during recruitment. The **Data & Statistics Team** will also respond to data queries generated by the **PIs, Project Coordinators**, or other study staff.

Statistical analyses and summary reports will be generated by the study **Biostatistician** during the course of the study. At the end of the study, the study Biostatistician will conduct analyses of the data and assist in preparation of study publications and presentations. The **Data Manager** will provide technical and data support for the Biostatistician throughout the study.

16.5 Study Records Retention

Study documents should be retained for 6 years after the completion of the study. These documents may be retained for a longer period, however, if required by local regulations or determined necessary by the NIDCR Medical Monitor, **NIDCR PO**, or **UHCMC IRB**. No records will be destroyed without the written approval of the **NIDCR**.

16.6 Protocol Deviations

A protocol deviation is any noncompliance with the clinical study protocol, Good Clinical Practice, or Manual of Procedures requirements. The noncompliance may be on the part of the subject, the investigator, or study staff (e.g., Project Coordinators, Outreach Workers). As a result of deviations, corrective actions are to be developed by the PI and/or Project Coordinator, and implemented promptly.

These practices are consistent with investigator and sponsor obligations in ICH E6:

- Compliance with Protocol, Sections 4.5.1, 4.5.2, 4.5.3, and 4.5.4.
- Quality Assurance and Quality Control, Section 5.1.1
- Noncompliance, Sections 5.20.1 and 5.20.2.

All deviations from the protocol must be addressed in study subject source documents and promptly reported to NIDCR and the UHCMC and/or UW IRBs, according to their requirements.

17 PUBLICATION POLICY

This study will comply with the [NIH Public Access Policy](#), which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive [PubMed Central](#) upon acceptance for publication. The Executive Committee will be responsible for developing publication procedures, resolving authorship issues, and informing the NIDCR Program Official regarding potential publications or presentations.

The International Committee of Medical Journal Editors (ICMJE) member journals have adopted a clinical trials registration policy as a condition for publication. The ICMJE defines a clinical trial as any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical interventions include drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, and the like. Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. The ICMJE policy requires that all clinical trials be registered in a public trials registry such as [ClinicalTrials.gov](#), which is sponsored by the National Library of Medicine. Other biomedical journals are considering adopting similar policies. For interventional clinical trials performed under NIDCR grants and cooperative agreements, it is the grantee's responsibility to register the trial in an acceptable registry, so the research results may be considered for publication in ICMJE member journals. The ICMJE does not review specific studies to determine whether registration is necessary; instead, the committee recommends that researchers who have questions about the need to register err on the side of registration or consult the editorial office of the journal in which they wish to publish.

[U.S. Public Law 110-85](#) (Food and Drug Administration Amendments Act of 2007 or FDAAA), Title VIII, Section 801 mandates that a "responsible party" (i.e., the sponsor or designated principal investigator) register and report results of certain "applicable clinical trials;" *NIH grantees must take specific steps to ensure compliance with NIH implementation of FDAAA.*

Additionally, we will follow the publication policies outlined in the Cooperative Agreement Terms and Conditions from NIDCR as excerpted below:

Each publication, press release or other document that cites results from NIH grant-supported research must include an acknowledgment of NIH grant support and disclaimer such as "The project described was supported by Award Number TBD from the National Institute of Dental & Craniofacial Research. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Dental & Craniofacial Research or the National Institutes of Health."

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SUPPLEMENTAL MATERIALS

These documents are relevant to the protocol, but they are not considered part of the protocol. They are stored and modified separately. As such, modifications to these documents do not require protocol amendments.

- *Manual of Procedures*
- *Case report forms*
- *Statistical Analysis Plan*

APPENDIX A: Schedule of Events

	Screening	Study Visit 1	Study Visit 2	Study Visit Final (7-8 months after initial)	Premature
Signed Consent/Accent Form					
Assessment of Eligibility Criteria	X	X			
Study Intervention – Referral Letters		X			
Questionnaires (IPQ-RD, Caregiver), demographic info		X	X	X	X
School dental examinations					
Person contact	X	X			
Telephone contact	X	X	X	X	(X)
Mail contact			X	X	(X)
Assessment of Adverse Events			(X)	(X)	(X)

(X) – As indicated/appropriate

APPENDIX B: Consent forms

- 1. UHCMC Consent form**
- 2. UHCMC Assent form**
- 3. UHCMC Consent form (examiner training)**
- 4. UHCMC Assent form (examiner training)**
- 5. UHCMC Consent form (Spanish)**
- 6. UHCMC Assent form (Spanish)**

**UNIVERSITY HOSPITALS
CASE MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES**
(v. 11.2012)
Reliant IRB: University of Washington

Project Title: Family Intervention with Caregivers of Children with Dental Needs

Principal Investigator: Suchitra Nelson, PhD
University of Washington PIs: Peter Milgrom, DDS and Joana Cunha-Cruz, DDS, MPH, PhD

Introduction/Purpose

We are asking you and your child to be in a research study. This form gives you information to help you decide if you want to participate. Please read the form carefully. Ask as many questions as you need to about anything that is not clear or does not give you enough information to make a decision. When all your questions have been answered, you can decide if you and your child want to be in the study. This process is called "informed consent."

The purpose of the study is to find out if different referral letters and a dental information guide will help parents/caregivers of children with tooth decay (cavities) take their child to the dentist for treatment. Our goal is to understand parents'/caregivers' views of their children's tooth decay and any problems they have getting dental care. With this information we can work with parents/caregivers so that they can help their children prevent tooth decay.

Your child is being asked to be in the study because he/she is in kindergarten, 1st, 2nd, 3rd, or 4th grade in the East Cleveland City School District. This dental study is also being done in Cowlitz and Lewis counties in Washington state.

You and your child's participation in this study are voluntary. By signing this consent form, you are agreeing to participate and giving us permission to contact you throughout the study (this school year). About 2,217 children and parent/caregivers will take part in this study from two sites, with about 765 from the East Cleveland site and 1,452 from the Washington sites.

If you and your child choose to participate, you will both take part in the study activities described below.

Study Procedures

All children will receive:

- Dental baseline screening exam at the beginning of the school year during regular school hours at your child's school. You may choose to come to the school during the screening if your child would like to have you there. A licensed dentist will ask your child to open his/her mouth and will examine your child's teeth with a light and disposable mirror just like in a dental office. This will not hurt your child. Each child will get a tooth brush, tooth paste, and tooth care instructions.
- Referral letter with the results of the dental screening will be sent home with your child and by mail. If your child has an urgent dental problem, you will be contacted by the study staff or the school to take him/her for dental care immediately. If your child has non-urgent cavities, then you will be contacted for further participation in the study.

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Parent/caregivers:

Before the dental baseline screening:

- Fill out a form asking for your contact information and a short health history for your child.
- Fill out two surveys that ask questions about your age, race and ethnicity, occupation, education level, beliefs about tooth decay, oral hygiene behaviors, and access to dental care. This will take about 20-25 minutes. If you do not want to answer a question you may skip it.

After the dental baseline screening:

- If your child has no cavities you and your child's participation will end.
- If your child is found to have cavities, you will:
 - Receive one of five types of referral letters (with or without a dental information guide) that will help you find dental care for your child. The type of letter you receive will be randomly selected (like flipping a coin).
 - Fill out a second set of surveys (similar to the ones you previously filled out) less than one month after the dental screening which will take about 25 minutes. These will be mailed to you with a self-addressed stamped envelope so that you can mail them back to us.
 - Possibly be selected at random (like flipping a coin) to fill out the same second set of surveys within a month after the dental screening, to check the accuracy of responses. The survey will also be mailed to you with a self-addressed stamped envelope so that you can mail them back to us.
 - Fill out a third set of surveys (similar to the ones you previously filled out) which will take about 25 minutes. These will be mailed to you with a self-addressed stamped envelope prior to your child's follow-up dental exam in May.
 - Your child will receive a dental follow-up screening exam at the end of the school year similar to the beginning of the school year.
- If your child needs immediate attention for cavities, a referral will be provided and your participation will end.
- You may be contacted by telephone by our staff to make sure surveys and letters were received. Some of these calls may be recorded for quality assurance purposes.

Risks

There is no known risk with being in this study. Some people are uncomfortable answering questions about themselves for research. We will try to make you feel as comfortable as possible. There is

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always a chance that information can be lost but we will use every precaution to protect the information.

Benefits

Your child may benefit if you learn about his/her dental problems. If your child has tooth decay, we will give you a referral letter to take with you when you go to the dentist or dental clinic for follow-up dental care. Your child may also benefit by learning how to take care of his/her teeth.

You may benefit from the dental information and facts that we provide for getting dental care. Also, you will provide us with valuable information that we will use to help parents/caregivers prevent tooth decay in their children.

Alternatives to Study Participation

You and your child may choose not to participate in this study. However, participating in this study will not affect you or your child's medical or dental benefits.

Financial Information

There is no cost to you or your insurance for participation in this study. You will receive a \$5 gift card and a tooth care kit (tooth brushes, tooth paste, and floss) for your family after you fill out the first set of surveys. If you are eligible to continue to participate after your child's dental screening (see study procedures) then you will receive a \$5 gift card after you fill out the second set of surveys (one month after the screening), and a \$10 gift card after you fill out the third set of surveys (at the end of the school year). If you are randomly selected to fill out the second set of surveys again, you will receive a \$5 gift card after you fill out the survey.

Confidentiality

All information will be used for study reasons only. Any phone call recordings will be destroyed within six weeks of the call. We will not give out your information or your child's information to any agency or person unless you ask for it to be shared. If the study results are published or presented, information from all of our participants will be presented as a group without the use of any names.

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled "**Family Intervention with Caregivers of Children with Dental Needs**" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI, and in what ways they can use the information. In order for the Principal Investigator (PI), Dr. Suchitra Nelson, sub-contract Principal Investigators (PIs), Dr. Peter Milgrom and Dr. Joana Cunha-Cruz, and the research study staff to collect and use your PHI, you must sign this Authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI

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is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals, Case Western Reserve University and the University of Washington who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you: 1) your child's name, age, gender, race and ethnicity, and school; 2) your name, age, race and ethnicity, address, home and cell telephone numbers, and email address; 3) results from your child's dental screening and exam; 4) your beliefs about tooth decay, oral hygiene behaviors, and access to dental care. This PHI will be used to improve dental visits for children who need follow-up dental care. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may be shared with the following groups/persons associated with this research study or involved in the review of research: 1) the Principal Investigator that is listed above as "Principal Investigator"; 2) Co-investigators at Case Western Reserve University (the Ohio site): Dr. Gerald Ferretti and Dr. Jeffrey Albert; 3) the sub-contract PIs at the University of Washington (the Washington site) which is jointly conducting the research study: Dr. Peter Milgrom and Dr. Joana Cunha-Cruz; 4) Research staff of the Departments of Community Dentistry and Oral Health Sciences at Case Western Reserve University and University of Washington, respectively; 5) other staff from the Principal Investigator's research group; 6) Harvard University subcontractor: Dr. Christine Riedy; 7) your insurance company; 8) The University Hospitals of Cleveland Institutional Review Board and any Institutional Review Board accrediting body; 9) University Hospitals, including the Center for Clinical Research and the Law Department; 10) National Institute of Dental and Craniofacial Research, the sponsor of the research study; 11) the Department of Health and Human Services, Office of Human Research Protections, and other national governmental agencies and regulatory agencies; 12) the National Committee for Quality Assurance and the Joint Commission for Accreditation of Healthcare Organizations; and 13) government representatives or federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to **Dr. Suchitra Nelson, Department of Community Dentistry, Case School of Dental Medicine, 2124 Cornell Road, Cleveland, Ohio 44106**. If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal

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Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Case Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Case Medical Center Institutional Review Board may review your study records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

_____ has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator, Dr. Suchitra Nelson, can be contacted at 216-368-3469. For the Washington sites, Dr. Peter Milgrom and Dr. Joana Cunha-Cruz can also be contacted at 206-685-4183 (Dr. Milgrom) or 206-685-6397 (Dr. Cunha-Cruz). If you have any questions, concerns, or complaints about the study in the future, you may also contact them later.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about concerns regarding the study; research participant's rights; research-related injury; or other human subject issues, please call the University Hospitals Case Medical Center's Research Subject Rights phone line at 216-983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Case Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

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Signature

Signing below indicates that you are 18 years of age or older and have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X	
Signature of Participant	Date
X	
Printed name of minor if used to obtain assent	
X	
Signature of Parent/Legal Guardian	Date
X	
Printed name of Parent/Legal Guardian	
X	
If Legal Guardian, indicate relationship to child	

X	
Signature of person obtaining informed consent	Date
X	
Printed name of person obtaining informed consent	
X	
Signature of Principal Investigator	Date
X	
Printed name of Principal Investigator	

**UNIVERSITY HOSPITALS CASE MEDICAL CENTER
ASSENT FOR INVESTIGATIONAL STUDIES**



IRB NUMBER: 01-14-15
IRB APPROVAL DATE: 03/17/2015
IRB EXPIRATION DATE: 03/09/2016

Reliant IRB: University of Washington

Study Title: Family Intervention with Caregivers of Children with Dental Needs

Principal Investigator: Suchitra Nelson, PhD

University of Washington PIs: Peter Milgrom, DDS and Joana Cunha-Cruz, DDS, MPH, PhD

What is a research study?

A research study is a way to find out new information about something. Children do not need to be in a research study if they don't want to.

Why are you being asked to be part of this research study?

You are being asked to take part in this research study because we are trying to learn more about tooth decay, or cavities. Cavities are a condition where teeth are attacked by bad germs that put holes in them and make them rot. We are inviting you to be in the study because we would like to help you in case you have cavities. We would like to help you see a dentist who can fix the holes in your teeth. About 2,217 children will be in this study.

Why is the study being done?

The results of the study will help us to understand if giving information to parents about cavities and dentists will help children who have cavities.

If you join the study what will happen to you?

We want to tell you about some things that will happen to you if you are in this study:

- A dentist will come to your school to check out your teeth once at the beginning of the school year and again at the end of the school year.
- Each time, the dentist will ask you to open your mouth and will look at your teeth with a light and a mirror just like at a dentist's office. This will take about 5 minutes.

Will any part of the study hurt?

This study will not make you hurt.

Will the study help you?

This study will help you know if you have cavities. We do not know if your cavities will get better because you take part in this study, although we hope this happens.

Will the study help others?

This study might find out things that will help other children with cavities someday.

Do my parents know about this study?

This study was explained to your parents and they said that we could ask you if you want to be in it. You can talk this over with them before you decide.

Who will see the information collected about you?

- The information collected about you during this study will be kept safely locked up. Nobody will know it except the people doing the research.
- The study information about you will be given to your parents.

UNIVERSITY HOSPITALS CASE MEDICAL CENTER 
ASSENT FOR INVESTIGATIONAL STUDIES

Reliant IRB: University of Washington

IRB NUMBER: 01-14-15
IRB APPROVAL DATE: 03/17/2015
IRB EXPIRATION DATE: 03/09/2016

Study Title: Family Intervention with Caregivers of Children with Dental Needs

Principal Investigator: Suchitra Nelson, PhD

University of Washington PIs: Peter Milgrom, DDS and Joana Cunha-Cruz, DDS, MPH, PhD

What do you get for being in the study?

You will get a tooth brush and tooth paste after the dentist looks at your teeth at the beginning of the school year and again at the end of the school year.

Will it cost anything to be in the study?

It will not cost you or your parents any money if you join the study.

Do you have to be in the study?

- You do not have to be in the study. No one will be upset if you don't want to do this study. If you don't want to be in this study, you just have to tell us. It's up to you.
- You can also take more time to think about being in the study.

What if I have any questions?

- You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call Dr. Nelson at (216) 368-3469. For the Washington sites you can call Dr. Milgrom at (206) 685-4183 or Dr. Cunha-Cruz at (206) 685-6397.
- You can also take more time to think about being in the study and also talk some more with your parents about being in the study.

What choices do you have if you say no to this study?

- There are other ways to help your cavities if you don't want to be in this study. For example, you can go to your dentist that your parents usually take you to.
- This study is extra, so if you don't want to do it nothing else will change.

Other information about the study:

- If you decide to be in this study, please write your name below.
- You can change your mind and stop being part of it at any time. All you have to do is tell the person in charge.
- You will be given a copy of this paper to keep.

Write your name

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Witness

Date

Person Obtaining Assent

Date



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Project Title: Family Intervention with Caregivers of Children with Dental Needs

Principal Investigator: Suchitra Nelson, PhD
 University of Washington PIs: Peter Milgrom, DDS and Joana Cunha-Cruz, DDS, MPH, PhD

Introduction/Purpose

Your child is being asked to participate in a research study to train dental examiners to recognize tooth decay consistently and accurately. This form gives you information to help you decide if you want your child to participate. Please read the form carefully. Ask as many questions as you need to about anything that is not clear or does not give you enough information to make a decision. When all your questions have been answered, you can decide if you want your child in the study. This process is called "informed consent."

This examiner training is part of a larger study aimed at finding out if different referral letters and a dental information guide will help parents/caregivers of children with tooth decay (cavities) take their child to the dentist for treatment. A total of 70 subjects between the ages of 5-18 years free of major medical problems will be required for the training session.

Your child was selected as a possible participant because he/she attends the Tapper Pediatric Dental Clinic at University Hospitals or the Case School of Dental Medicine's Pediatric Clinic. You will be contacted by Dr. Nelson or her staff for your child's participation in this study.

Your child's participation in this study is voluntary and refusal to participate will not involve penalty or loss of benefit of medical or dental care.

Study Procedures

If you agree to let your child participate in this study, your child will be examined by the dental examiners. The dental examination will take place at the Pediatric Dental Clinic at the Case School of Dental Medicine. The following is a description of the study procedures:

Dental examination of teeth by licensed dentists. Your child will be asked to open their mouth, and their teeth will be examined with a light and mirror as is done routinely in a dentist office. The exam will take approximately 45 minutes. There is no discomfort with the procedure.

Risks

There is no known risk with being in this study. However, your child may experience some discomfort during the exam from sitting in the dental chair for some time. The dental exam is routinely performed in a dental office.

Benefits

Your child may not directly benefit from participating in this study.



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Alternatives to Study Participation

You may choose to not have your child participate in this study.

Financial Information

There is no cost to you or your insurance for participation in this study. You will be given \$20 for your child's participation in this study and \$5 to help with the cost of transportation.

Confidentiality

All information will be used for study reasons only. All subjects will be given an ID number. All study identifiers will be maintained in the PI's office in a locked cabinet. We will not give out your information or your child's information to any agency or person unless you ask for it to be shared. If the study results are published or presented, information from all of our participants will be presented as a group without the use of any names.

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled "Family Intervention with Caregivers of Children with Dental Needs" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI, and in what ways they can use the information. In order for the Principal Investigators (PIs) and the research study staff to collect and use your PHI, you must sign this Authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals, Case Western Reserve University and the University of Washington who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI: 1) your child's name, date of birth, gender; 2) results from your child's dental clinical exam; 3) your name, home telephone number and cell telephone number. This PHI will be used to train dentist examiners in recognizing dental caries in children correctly. Your access to your PHI may be limited during the study to protect the study results.



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Principal Investigator: Suchitra Nelson, PhD University of Washington PIs: Peter Milgrom, DDS and Joana Cunha-Cruz, DDS, MPH, PhD	

Your PHI may be shared with the following groups/persons associated with this research study or involved in the review of research: 1) the Principal Investigator that is listed above as "Principal Investigator"; 2) Co-investigators at Case Western Reserve University (the Ohio site): Dr. Gerald Ferretti and Dr. Jeffrey Albert; 3) the sub-contract PIs at the University of Washington (the Washington site) which is jointly conducting the research study: Dr. Peter Milgrom and Dr. Joana Cunha-Cruz; 4) Research staff of the Departments of Community Dentistry and Oral Health Sciences at Case Western Reserve University and University of Washington, respectively; 5) other staff from the Principal Investigator's research group; 6) Harvard University subcontractor: Dr. Christine Riedy; 7) your insurance company; 8) The University Hospitals of Cleveland Institutional Review Board and any Institutional Review Board accrediting body; 9) University Hospitals, including the Center for Clinical Research and the Law Department; 10) National Institute of Dental and Craniofacial Research, the sponsor of the research study; 11) the Department of Health and Human Services, Office of Human Research Protections, and other national governmental agencies and regulatory agencies; 12) the National Committee for Quality Assurance and the Joint Commission for Accreditation of Healthcare Organizations; and 13) government representatives or federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Suchitra Nelson, Department of Community Dentistry, Case School of Dental Medicine, 2124 Cornell Road, Cleveland, Ohio 44106. If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If



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Project Title: Family Intervention with Caregivers of Children with Dental Needs

Principal Investigator: Suchitra Nelson, PhD

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you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Case Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Case Medical Center Institutional Review Board may review your study records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator, Dr. Suchitra Nelson, can be contacted at 216-368-3469.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about: concerns regarding the study; research participant's rights; research-related injury; or other human subject issues, please call the University Hospitals Case Medical Center's Research Subject Rights phone line at 216-983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Case Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.



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Signature

Signing below indicates that you are 18 years of age or older and have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

<input checked="" type="checkbox"/>	
	Signature of Participant
<input checked="" type="checkbox"/>	
	Printed name of minor if used to obtain assent
<input checked="" type="checkbox"/>	
	Signature of Parent/Legal Guardian
<input checked="" type="checkbox"/>	
	Printed name of Parent/Legal Guardian
<input checked="" type="checkbox"/>	
	If Legal Guardian, indicate relationship to child

Study personnel (only individuals designated on the checklist may obtain consent)

<input checked="" type="checkbox"/>	
	Signature of person obtaining informed consent
<input checked="" type="checkbox"/>	
	Printed name of person obtaining informed consent
<input checked="" type="checkbox"/>	
	Signature of Principal Investigator
<input checked="" type="checkbox"/>	
	Printed name of Principal Investigator

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What is a research study?

A research study is a way to find out new information about something. Children do not need to be in a research study if they don't want to.

Why are you being asked to be part of this research study?

You are being asked to take part in this research study because we are trying to learn more about tooth problems or cavities. Tooth decay is a condition where teeth are attacked by bad germs that put holes in them and make them rot. We are inviting you to be in the study because we would like our dentists to be more familiar with tooth problems. About 70 children will be in this study.

Why is the study being done?

The results of the study will help us to understand if teaching the dentists will help children who have tooth decay.

If you join the study what will happen to you?

We want to tell you about some things that will happen to you if you are in this study:

- You will be asked to come to see the dentists doing this study one time and you will need to stay for about 45 minutes.
- We will ask you to open your mouth, and the dentists will look at your teeth with a mirror and light.

Will any part of the study hurt?

This study will not make you hurt. But, sitting in the dental chair for a long time may make you feel uncomfortable.

Will the study help you?

This study will not help you.

Will the study help others?

You will help the dentists to be more familiar with tooth decay that will help other children.

Do my parents know about this study?

This study was explained to your parents and they said that we could ask you if you want to be in it. You can talk this over with them before you decide.

Who will see the information collected about you?

- The information collected about you during this study will be kept safely locked up. Nobody will know it except the people doing the research.
- The study information about you will be given to your parents.

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IRB EXPIRATION DATE: 03/09/2016**Study Title:** Family Intervention with Caregivers of Children with Dental Needs**Principal Investigator:** Suchitra Nelson, PhD**University of Washington PIs:** Peter Milgrom, DDS and Joana Cunha-Cruz, DDS, MPH, PhD**What do you get for being in the study?**

You and your parents will get \$20 for the study and \$5 to help with the cost of transportation.

Will it cost anything to be in the study?

It will not cost you or your parents any money if you join the study.

Do you have to be in the study?

- You do not have to be in the study. No one will be upset if you don't want to do this study. If you don't want to be in this study, you just have to tell us. It's up to you.
- You can also take more time to think about being in the study.

What if I have any questions?

- You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call Dr. Nelson at (216) 368-3469.
- You can also take more time to think about being in the study and also talk some more with your parents about being in the study.

What choices do you have if you say no to this study?

This study is extra, so if you don't want to do it nothing else will change and there are no other choices.

Other information about the study:

- If you decide to be in this study, please write your name below.
- You can change your mind and stop being part of it at any time. All you have to do is tell the person in charge.
- You will be given a copy of this paper to keep.

Write your name

Witness

Date

Person Obtaining Assent

Date

**HOSPITALES UNIVERSITARIOS DEL
CENTRO DE CASO MEDICO PARA EL
CONSENTIMIENTO DE ESTUDIOS DE
INVESTIGACION**

(v. 11.2012)

Dependiente IRB: Universidad de Washington

Titulo del Proyecto: Intervención Familiar con los Cuidadores de los Niños/as con Necesidades Dentales

Investigador Principal: Suchitra Nelson, PhD
Universidad de Washington PIs: Peter Milgrom, DDS and Joana Cunha-Cruz, DDS, MPH, PhD

Introducción/Propósito

Le estamos pidiendo a usted y a su niño/a que estén en un estudio de investigación. Este formulario le da información para ayudarle a decidir si usted quiere participar. Por favor lea cuidadosamente el formulario. Haga todas las preguntas que necesite acerca de cualquier cosa que no esté claro o no le de suficiente información para tomar una decisión. Cuando todas sus preguntas hayan sido contestadas, usted puede decidir si usted y su niño/a quieren estar en el estudio. Este proceso se llama "consentimiento informado."

El propósito del estudio es encontrar si diferentes cartas de referencias y una guía de información dental le ayudaría a los padres/cuidadores de los niños/as con caries (cavidades) en los dientes a llevar a sus niños/as al dentista para tratamiento. Nuestra meta es entender la visión de los padres/cuidadores acerca de las caries de sus niños/as y algunos problemas que tienen para obtener cuidado dental. Con esta información podemos trabajar con padres/cuidadores para que puedan ayudar a sus niños a prevenir caries en el diente.

Se le ha pedido a su niño/a a ser parte de este estudio porque él/ella están en el kinder, 1o. 2o., 3o, o 4o grado en la Escuela del Distrito de la Ciudad Este de Cleveland. Este estudio dental también se está haciendo en los condados de Cowlitz y Lewis en el estado de Washington.

La participación de usted y su niño/a en este estudio son voluntarias. Firmando este formulario de consentimiento, usted está aceptando participar y nos da la promesa de contactarle durante todo el estudio (de este año escolar). Alrededor de 2,217 niños/as y padres/cuidadores en dos sitios serán parte de este estudio, con aproximadamente 765 sitios en el Este de Cleveland, y 1,452 en el sitio de Washington.

Si usted y su niño/a eligen a participar, los dos tomarán parte en las actividades del estudio que se describen a continuación.

Procedimiento del Estudio

Todos los niños/as recibirán:

- Evaluación dental, un examen que es el punto de referencia, al inicio del año escolar durante el horario escolar, en la escuela de su niño/a. Usted puede elegir venir a la escuela durante la revisión si a su niño/a le gustaría tenerlo allí. Un dentista con licencia le pedirá a su niño/a que abra su boca y examinará los dientes a su niño/a, con una luz y un espejo desechable, igual

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como en la oficina dental. Esto no le hará daño a su niño/a. Cada niño/a obtendrá un cepillo, pasta de dientes e instrucciones de cuidado de sus dientes.

- Se le mandará una carta de referencia con los resultados de la revisión dental con su niño/a a la casa y por correo. Si su niño/a tiene un problema dental urgente, usted será contactado por la personal del estudio o de la escuela para que lo/la lleve inmediatamente al cuidado dental. Si su niño/a tiene caries que no son urgentes, entonces usted será contactado para futura participación en el estudio.

Padres/cuidadores

Que es el punto de referencia antes del examen:

- Llene un formulario pidiéndole información de contacto y una pequeña historia de salud de su niño/a
- Llene dos cuestionarios acerca de su edad, raza y etnicidad, ocupación, nivel de educación, creencia acerca de la caries de dientes, comportamientos de higiene oral, y acceso al cuidado dental. Esto tomará aproximadamente 20-25 minutos. Si usted no quiere contestar una pregunta la puede pasar.

Que es el punto de referencia después del examen:

- Si su niño/a no tiene caries la participación de usted y de su niño/a terminaría.
- Si se le encuentran caries a su niño/a, usted hará:
 - Recibirá una de las 5 tipos de cartas de referencia (con o sin una guía de información dental) que le ayudará a encontrar el cuidado dental para su niño/a. El tipo de carta que reciba será seleccionada al azar (como cara o cruz).
 - Llene un segundo grupo de cuestionarios (similar a los que llenó previamente) al menos un mes después de la revisión dental, el cual tomará aproximadamente de 25 minutos. Estos se le enviarán vía correo con un sobre con la dirección de retorno y estampilla así usted nos lo pueda mandar de regreso.

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- o Posiblemente será seleccionado al azar (como cara o cruz) para llenar el mismo grupo de cuestionarios un mes después de la revisión dental, para revisar la exactitud de las respuestas. El cuestionario también le será enviado por correo con un sobre con la dirección de retorno y estampilla así usted nos lo puede mandar de regreso.
- o Llene un tercer grupo de cuestionarios (similar a los que llenó previamente) el cual tomará aproximadamente de 25 minutos. Estos serán enviado por correo con un sobre con la dirección de retorno y estampilla antes del examen de seguimiento dental para su niño/a en Mayo.
- o Su niño/a recibirá un examen de evaluación de seguimiento al final del año escolar similar a la del inicio del año escolar.
- Si su niño/a necesita asistencia inmediata para las caries, una referencia será proporcionada y su participación terminará.
- Usted podría ser contactado por teléfono por nuestro personal para asegurarnos que las encuestas y cartas fueron recibidas. Algunas de estas llamadas podrían ser grabadas para propósitos de garantía de calidad.

Riesgos

No se conocen riesgos al estar en este estudio. Algunas personas se incomodan respondiendo preguntas acerca de ellos mismos para la investigación. Trataremos de hacerlo sentir tan cómodo como sea posible. Siempre hay una oportunidad que la información puede perderse pero usaremos cada precaución para proteger la información.

Beneficios

Si su niño/a podría beneficiarse si usted aprende acerca de sus problemas dentales. Si su niño/a tiene caries en los dientes, le daremos una referencia para que lleve con usted cuando vaya al dentista o clínica dental para cuidado de seguimiento dental. Su niño/a se podría beneficiar al aprender como cuidar sus dientes.

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Usted podría beneficiarse de la información y hechos que nosotros proveeremos para obtener cuidado dental. También, usted nos dará una valiosa información que utilizaremos para ayudarle a los padres/cuidadores para prevenir la caries de los dientes en los niños/as.

Alternativas para la Participación del Estudio

Usted y su niño/a podrían elegir a no participar en este estudio. Sin embargo, participar en este estudio no le afectará a usted o los beneficios médicos o dentales a su niño/a

Información Financiera

No tiene ningún costo para usted o su seguro por participar en este estudio. Usted recibirá \$5.00 en tarjeta de regalo y un paquete de cuidado dental (cepillos, pasta e hilo dental) para su familia después que haya llenado el primer grupo de cuestionarios. Si usted es elegible para continuar participando después de la revisión dental de su niño/a (vea el procedimiento del estudio) entonces recibirá una tarjeta de regalo de \$5.00 después que usted llene el segundo grupo de cuestionarios (un mes después de la revisión), y una tarjeta de regalo de \$10.00 después que haya llenado el tercer grupo de cuestionarios (al final del año escolar). Si usted es seleccionado al azar para llenar de nuevo el segundo grupo de cuestionarios, usted recibirá una tarjeta de \$5.00 después que haya llenado el cuestionario.

Confidencialidad

Toda la información se utilizará únicamente para el estudio. Cualquier grabación de llamadas telefónicas será destruida dentro de las siguientes ocho semanas después de la llamada. No daremos su información o la de su niño/a a ninguna agencia o persona al menos que usted pida que se comparta. Si los resultados del estudio son publicados o presentados, la información de todos los participantes serán presentadas en grupo sin el uso de nombres.

Privacidad de Información de Salud Protegida

La ley del seguro médico de portabilidad y responsabilidad (HIPAA por sus siglas en inglés) es una ley federal que ayuda a proteger la privacidad de su información de salud y para con quien esta información se pueda compartir dentro o fuera de los Hospitales de la Universidad. Este formulario de Autorización es específicamente para un estudio de investigación autoriza "Intervención Familiar con el Cuidador de los Niños/as con Necesidades Dentales" y les dirá que información de salud (llamado Protección de información de salud o PHI por sus siglas en

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CENTRO DE CASO MEDICO PARA EL
CONSENTIMIENTO DE ESTUDIOS DE
INVESTIGACION**

(v. 11.2012)

Dependiente IRB: Universidad de Washington

Titulo del Proyecto: Intervención Familiar con los Cuidadores de los Niños/as con Necesidades Dentales

Investigador Principal: Suchitra Nelson, PhD
Universidad de Washington PIs: Peter Milgrom, DDS and Joana Cunha-Cruz, DDS, MPH, PhD

inglés) será colectadas para este estudio de investigación, quienes verán su PHI, y de que manera ellos podrán usar esta información. En orden para que el investigador principal (PI), Dr. Suchitra Nelson, y el subcontrato principal de investigadores Dr. Peter Milgrom and Dr. Joana Cunha-Cruz, y el personal del estudio de investigación para colectar y usar su PHI, usted deberá de firmar este formulario de autorización.

Usted recibirá una copia de esta autorización firmada para sus archivos. Si usted no firma este formulario usted no podría unirse a este estudio. Su decisión de permitir usar y revelar su PHI es voluntario y no tendrá impacto en su tratamiento en los Hospitales de la Universidad. Firmando este formulario, usted está permitiendo a los investigadores de este estudio de usar y revelar su PHI en la manera descrita

Generalmente el investigador principal y el personal del estudio en los Hospitales de la Universidad, Case Western Reserve University (La Reserva de la Universidad de los Casos del Occidente) y University of Washington (Universidad de Washington) quienes están trabajando en este proyecto de investigación, sabrán que usted está en el estudio de investigación y verán y utilizarán su PHI. Los investigadores que trabajen en este estudio reunirán el siguiente PHI de usted: 1) el nombre de su niño/a, edad, genero, raza y etnicidad, y escuela; 2) su nombre, edad, raza y etnicidad, dirección, numero de teléfono de casa y celular y dirección de correo electrónico; 3) resultados de las revisiones dentales de sus niño/a y examen; 4) sus creencias acerca de la caries en los dientes, comportamiento de higiene oral, y acceso a cuidado dental. Este PHI será usado para mejorar visitas dentales para niños/as quienes necesitan de dar seguimiento de cuidado dental. El acceso a su PHI podría ser limitado durante el estudio para proteger los resultados del estudio.

Su PHI podrá ser compartida con los siguientes grupos/personas asociadas con este estudio de investigación o envuelto en la revisión de investigación: 1) el Investigador Principal que está mencionado a continuación como: "Investigador Principal"; 2) Co-Investigador en la Universidad de Case Western Reserve (del sitio de Ohio): Dr. Gerald Ferretti y Dr. Jeffrey Albert; 3) el Sub-Contrato del PIs en la Universidad de Washington (en el sitio de Washington) el cual es conducido en conjunto con del estudio de investigación: Dr. Peter Milgrom y Dr. Joana Cunha-Cruz; 4) el Personal de investigación del Departamento de la Comunidad de Odontología y Ciencia de Salud Dental en la Case Western Reserve University (La Reserva de la Universidad de los Casos del Occidente) y University of Washington (Universidad de Washington), respectivamente; 5) otro personal del Investigador Principal del grupo de investigación; 6) Subcontratado por la Universidad de Harvard, Dr. Christine Riedy; 7) su compañía de seguro; 8) Los Hospitales de la Universidad de la Junta de Revisión Institucional de Cleveland y cualquier

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Junta de Revisión Institucional de cuerpo acreditado; 9) Hospitales de las Universidades, incluyendo el Centro de Investigación Clínica y el Departamento de Ley; 10) Institución Nacional de Investigación Dental y Craneofacial, el patrocinador del estudio de investigación; 11) el Departamento de Servicios Humanos y de Salud, Oficina de Protección de Investigación Humana y otras agencias gubernamentales nacionales y agencias de regulación; 12) el Comité Nacional de Seguro de Calidad y la Comisión Conjunta para la Acreditación de las Organizaciones de Cuidado de Salud; y 13) representantes de gobierno o agencias federales, cuando son requeridos por ley.

Su permiso para usar y divulgar su PHI no se vence. Sin embargo, usted tiene el derecho de cambiar su opinión en cualquier momento y remover su autorización. Si usted remueve su autorización, los investigadores continuarán usando la información que ellos colectaron previamente, pero ellos no colectaran ninguna información adicional. También si usted ya no puede ser capaz de participar en el estudio de investigación. Al remover su permiso, usted deberá hacerlo por escrito enviando una carta a **Dr. Suchitra Nelson, Department of Community Dentistry, Case School of Dental Medicine, 2124 Cornell Road, Cleveland, Ohio 44106**. Si tiene una queja o preocupación acerca de la privacidad de su información de salud, usted podría escribir a la UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 o a el Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Las quejas deberían ser enviadas entre 180 días después de encontrar el problema.

Los investigadores y personal están de acuerdo a proteger su información de salud mediante solo el uso y divulgación de lo permitido por usted en esta Autorización y como dirigido por la ley del estado y federal. Los Hospitales de la Universidad están comprometidos a proteger su confidencialidad. Por favor entienda que una vez su PHI haya sido divulgada a cualquiera fuera de los Hospitales de la Universidad, hay un riesgo que su PHI no se puede proteger; sin embargo otras leyes del estado y federales podrían continuar protegiendo su información.

Resumen de sus derechos como participante en este estudio de investigación

Su participación en este estudio de investigación es voluntario. El rehusar a participar no alterará su cuidado de salud usual o involucrará ninguna pena o la perdida de beneficios a los cuales de lo contrario usted tiene derecho. Si usted decide unirse al estudio, usted podrá retirarse en cualquier momento y por cualquier razón sin pena o perdida de beneficios. Si información se

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generá de este estudio y es publicada o presentada, su identidad no será revelada. En el evento que nueva información llegue a estar disponible que pudiera afectar el riesgo o beneficios asociadas con este estudio o su buena voluntad de participar en ella, usted será notificado para que pueda decidir si o no continua participando. Si usted experimenta daño físico o enfermedad como resultado de participar en este estudio de investigación, cuidado medico estará disponible en los Hospitales de la Universidad, Centro de Caso Medico (UHCMC por sus siglas en ingles) o en otro lado; sin embargo el UHCMC no tiene planes de proveer cuidado gratis o compensación por los salarios perdidos.

Divulgación de sus archivos del estudio

Se harán esfuerzos para guardar la información persona en sus expedientes de investigación privados y confidenciales, pero completa confidencialidad no puede ser garantizada. Los Hospitales de la Universidad, Centro de Caso Medico Junta de Revisión Institucional revisará sus expedientes del estudio. Ademas, para estudios de tratamientos, el patrocinador del estudio y posiblemente agencias reguladoras del extranjero podrían revisar sus expedientes. Si sus expedientes son revisados su identificación podría ser conocida.

Información de contacto

_____ le ha descrito que es lo que se va a ser, los riesgos, peligros y beneficios envueltos . El investigador Principal Dr. Suchitra Nelson, puede ser contactado al 216-368-3469. Por el sitio de Washington, Dr. Peter Milgrom y Dr. Joana Cunha-Cruz pueden ser también contactados al 206-685-4183 (Dr. Milgrom) o 206-685-6397 (Dr. Cunha-Cruz). Si en el futuro tiene algunas preguntas, preocupaciones o quejas acerca del estudio, usted podría contactarlos mas tarde.

Si los investigadores no pueden ser contactados, o si usted le gustaría hablar con alguien mas aparte de los investigador/es acerca de: preocupaciones acerca del estudio; los derechos del participante en la investigación; daño relacionado con la investigación; o otro tema del ser sujeto humano, por favor llame a los Hospitales de la Universidad, Centro de Caso Medico línea de teléfono para Derecho de Sujetos de Investigación, al 216-983-979 o escriba al: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Case Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061

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Firma

Firmando a continuación indica que usted es mayor de 18 años de edad y que ha sido informado acerca del estudio de investigación en el cual usted está de acuerdo voluntariamente a participar; que usted ha hecho preguntas acerca del estudio que usted podría tener; y que la información que se le ha dado le ha permitido hacer un informe completo y decisión libre acerca de su participación en el estudio. Al firmar este formulario de consentimiento, usted no renuncia a cualquier derecho legal, y los investigadores o patrocinadores no están exentos de cualquier responsabilidad que puedan tener. Se le dará una copia de este formulario de consentimiento.

X	
Firma del Participante	Fecha
X	
Nombre impreso del menor si se utiliza para obtener el asentimiento	
X	
Firma del Padre / Tutor Legal	Fecha
X	
Nombre impreso del padre / tutor legal	
X	
Si tutor legal, indican relación con el niño	

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Personal del estudio (solo individuos designados en la lista de control podrían obtener consentimiento)

X	
Firma de la persona que recibe el consentimiento	Fecha
X	
Escriba (en molde) el nombre de la persona que recibió el informe de consentimiento	
X	
Firma del Investigador Principal	Fecha
X	
Escriba (en molde) el nombre del Investigador Principal	

IRB NUMBER: 01-14-15

IRB APPROVAL DATE: 6/17/2015

IRB EXPIRATION DATE: 03/09/2016

HOSPITALES UNIVERSITARIOS DEL CENTRO DE INVESTIGACIÓN DE CASO

Dependiente de la junta de revisión institucional (IRB por sus siglas en Inglés)
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¿Que es un estudio de investigación?

- Un estudio de investigación es un camino a encontrar nueva información acerca de algo. Los niños/as no necesitan estar en el estudio de investigación si ellos no quieren.

¿Porque se le ha pedido a usted ser parte de este estudio de investigación?

- Se le ha pedido ser parte de este estudio de investigación porque necesitamos aprender mas acerca de la caries en los dientes. Las caries son una condición donde los dientes son atacados por gérmenes malos que pone hoyos en ellos y hace que se pudran. Nosotros le estamos invitando a ser parte del estudio porque nos gustaría ayudarle en caso que tenga caries. Nos gustaría ayudarle a ver a un dentista que pueda arreglar los hoyos en sus dientes. Alrededor de 2,217 niños/as estarán en este estudio.

¿Porque se esta haciendo este estudio?

- Los resultados del estudio nos ayudará a entender si le damos información a los padres acerca de las caries y los dentistas le ayudarán a los niños/as que tienen caries.

¿Que le va a pasar si usted se une al estudio?

Nosotros queremos decirle algunas cosas acerca de que le pasara si usted esta en este estudio:

- Un dentista vendrá a su escuela a revisar sus dientes una vez al inicio del año escolar y luego al final del año escolar.
- Cada vez, el dentista le pida que abra la boca y le vera sus dientes con una luz y un espejo, como en la oficina del dentista. Esto le tomara como 5 minutos.

¿Dolerá alguna parte de este estudio?

- Este estudio no le dolerá.

¿Le ayudará este estudio?

- Este estudio le ayudará saber si usted tiene caries. Nosotros no sabemos si sus caries se mejorarán porque usted sea parte en este estudio, aunque esperamos que eso suceda.

¿Le ayudara este estudio a otros?

- Este estudio podría encontrar cosas que pueden ayudar algún día a otros niños/as con caries

IRB NUMBER: 01-14-15
 IRB APPROVAL DATE: 6/17/2015
 IRB EXPIRATION DATE: 03/09/2016

HOSPITALES UNIVERSITARIOS DEL CENTRO  **DIJO PARA EL**
CONSENTIMIENTO DE ESTUDIOS DE INVESTIGACIÓN DE CASO

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¿Mis padres tienen conocimiento acerca de este estudio?

- Este estudio fue explicado a sus padres y ellos dijeron que podríamos preguntarte si le gustaría estar en el. Puedes hablar con ellos acerca de esto antes que decidas

¿Quien verá la información coleccionada acerca de usted?

- La información coleccionada acerca de usted durante este estudio será guardada con seguridad. Nadie lo sabrá excepto las personas que hacen la investigación
- La información del estudio acerca de usted se le dará a sus padres.

¿Que es lo que usted obtiene de este estudio?

- Obtendrá un cepillo y pasta de dientes después que el dentista vea sus dientes al inicio y luego al final del año escolar.

¿Costará algo estar en el estudio?

- Si se une al estudio, no les costará nada ni a usted o a sus padres.

¿Tengo que estar en el estudio?

- Usted no tiene que estar en el estudio. Nadie se molestará si usted no lo quiere hacer. Si no quiere estar en este estudio, usted solo nos tiene que decir. Todo depende de usted.
- Usted también puede tomar mas tiempo para pensar acerca de estar en el estudio.

¿Que pasa si tengo algunas preguntas?

- Usted puede preguntar cualquier pregunta que tenga acerca del estudio. Si tiene una pregunta mas tarde que no pensó ahora, usted puede llamar a Dr. Nelson al (216) 368-3469. Para los sitios de Washington, usted puede llamar al Dr. Milgrom al (206) 685-4183 o al Dr. Cunha-Cruz at (206) 685-6397.
- También usted puede tomarse mas tiempo para pensar acerca de estar en el estudio y hablar mas con sus padres acerca de estar en el estudio.

¿Que opciones tiene usted si dice no a este estudio?

- Si usted no quiere estar en este estudio, hay otras maneras de ayudar a sus caries. Por ejemplo, usted puede ir a su dentista al que usualmente sus padres lo llevan.
- Este estudio es adicional. Así que si usted no quiere hacerlo nada va a cambiar.



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Otra información acerca del estudio:

- Si usted decide estar en este estudio, por favor escriba su nombre abajo.
- Usted puede cambiar su decisión y parar de ser parte de este estudio en cualquier momento. Lo único que tiene que hacer es decirle a la persona que esta a cargo.
- Se le dará una copia de este papel para que lo guarde.

Escriba su nombre

Testigo

Fecha

Persona que obtiene el consentimiento

Fecha

APPENDIX C: IPQ-RD and Caregiver Questionnaire

In English:

- 1. Baseline IPQ-RD**
- 2. Baseline Caregiver Questionnaire**
- 3. 2-week Follow-up IPQ-RD**
- 4. 2-week Follow-up Caregiver Questionnaire**
- 5. Final Follow-up IPQ-RD**
- 6. Final Follow-up Caregiver Questionnaire**

In Spanish:

- 1. Baseline IPQ-RD**
- 2. Baseline Caregiver Questionnaire**
- 3. 2-week Follow-up IPQ-RD**
- 4. 2-week Follow-up Caregiver Questionnaire**
- 5. Final Follow-up IPQ-RD**
- 6. Final Follow-up Caregiver Questionnaire**

Site: _____ ID# _____

Family Access to Dentist Study

**Your Feelings
About Cavities**

January 29, 2015

Baseline IPQ-RD

Site: _____ ID# _____

Instructions:

We are interested in your views about your child's cavities (tooth decay). Please indicate how much you agree or disagree with the following statements about cavities by circling one of the following responses for each question: **strongly agree (1), agree (2), neither agree nor disagree (3), disagree (4), strongly disagree (5)**.

1. *Please tell us whether you believe each of the following is a symptom related to dental cavities in children:*

1a. Tooth pain	Yes	No
1b. Tooth sensitivity to hot or cold	Yes	No
1c. Hole in tooth	Yes	No
1d. Dark or white spot on tooth	Yes	No
1e. Swelling in face or gums (including a gum boil or abscess)	Yes	No

Please circle the number of the best answer for each question. If your child has not had cavities, please respond how you would if they did.

About your child:

Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
----------------	-------	----------------------------	----------	-------------------

2. Cavities in my child is a serious illness.	1	2	3	4	5
3. Cavities in my child has had a big effect on <u>his/her</u> life.	1	2	3	4	5
4. Cavities in my child has had a big effect on how <u>he/she</u> smiles.	1	2	3	4	5
5. Cavities in my child has had a big effect on <u>his/her</u> behavior at home.	1	2	3	4	5
6. Cavities in my child has had a big effect on <u>his/her</u> school work.	1	2	3	4	5
7. Cavities in my child has had a big effect on <u>his/her</u> self-worth.	1	2	3	4	5
8. Cavities in my child is disabling.	1	2	3	4	5

Site: _____ ID# _____

About you:	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
	1	2	3	4	5
9. Cavities in my child has a big impact on <u>my</u> life.	1	2	3	4	5
10. I cannot easily live with <u>my</u> child's cavities.	1	2	3	4	5
11. Cavities in my child has a big effect on how others see <u>me</u> .	1	2	3	4	5
12. Cavities in my child has caused money problems <u>for me</u> .	1	2	3	4	5
13. Cavities in my child has a big effect on <u>my</u> self-worth.	1	2	3	4	5

About your child:	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
	1	2	3	4	5
14. There is a lot that can be done to improve the cavities in <u>my child</u> .	1	2	3	4	5
15. <u>My child's</u> treatment will help make his/her cavities better.	1	2	3	4	5
16. Improvement in <u>my child's</u> cavities is not due to chance or fate.	1	2	3	4	5
17. <u>What my child</u> does decides if his/her cavities get better or worse.	1	2	3	4	5

About you:	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
	1	2	3	4	5
18. There is a lot <u>I can</u> do to control my child's cavity symptoms.	1	2	3	4	5
19. <u>What I do</u> decides if my child's cavities get better or worse.	1	2	3	4	5
20. There is a lot <u>I can</u> do to stop my child's cavities once they start.	1	2	3	4	5
21. There is a lot <u>I can</u> do to prevent cavities in my child.	1	2	3	4	5

Site: _____ ID# _____

About your child:

22. My child's cavities will not get better over time.
 23. Cavities in my child are likely to be long-lasting rather than short-term.

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
22.	1	2	3	4	5
23.	1	2	3	4	5

About your child:

24. Cavities in my child may change from time to time.
 25. There will be times when my child's cavity symptoms get worse and times when they get better.

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
24.	1	2	3	4	5
25.	1	2	3	4	5

About you:

26. I have a clear understanding of my child's cavities.
 27. My child's cavity symptoms are not confusing to me.

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
26.	1	2	3	4	5
27.	1	2	3	4	5

About you:

28. I get really sad and upset when I think about my child suffering from cavities.
 29. Seeing my child with cavities worries me.
 30. Seeing my child with cavities makes me feel angry.
 31. Seeing my child with cavities can make me feel helpless.

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
28.	1	2	3	4	5
29.	1	2	3	4	5
30.	1	2	3	4	5
31.	1	2	3	4	5

Site: _____ ID# _____

32. Causes of children's cavities:

We would like to know what you think caused your child's cavities. There is no correct answer. We are interested in your own ideas about the causes of your child's cavities rather than what others (including doctors or family) may have told you. Below is a list of possible causes.

Please tell us how much you agree or disagree with each cause by circling the number that best fits your answer: *strongly agree (1), agree (2), neither agree nor disagree (3), disagree (4), strongly disagree (5)*.

<i>Please circle the number of the best answer</i>	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
	1	2	3	4	5
32a. Stress or worry caused my child's cavities					
32b. Cavities runs in my family					
32c. A germ or virus caused my child's cavities					
32d. Diet or eating habits caused my child's cavities					
32e. Chance or bad luck caused my child's cavities					
32f. Poor dental care caused my child's cavities					
32g. Something I did as a parent caused my child's cavities					
32h. My negative thoughts caused my child's cavities					
32i. Family problems or worries caused my child's cavities					
32j. My feelings (feeling down, anxious) caused my child's cavities					
32k. My child's lack of ability to fight off infections caused his/her cavities					

Site: _____ ID#_____

33. Please list in order the three most important things that you now believe caused YOUR child's cavities. You may use any of the items from the previous question or you may have other ideas of your own.

The most important causes for me are:

1st _____

2nd _____

3rd _____

Family Access to Dentist Study

Caregiver Questionnaire	June 29, 2015
	Baseline

1

99

Study Site _____ ID# _____

Caregiver Questionnaire-Baseline

Date of Interview: _____
month day year

Interviewer's initials: _____

1. BACKGROUND INFORMATION**1.1 Your Age** _____ years**1.2 Your race and ethnicity.****1.2a Your race.** _____**1.2b Your ethnicity.** _____

Please mark with an X all that apply.

Please mark only one with an X.

Black _____

Not Hispanic/Latino _____

White _____

Hispanic/Latino _____

Asian _____

Unknown _____

Am. Indian/Alaskan _____

Hawaiian/Pacific Isl. _____

More than one race _____

Unknown _____

1.3 Your marital status.

Please mark only one with an X.

Married _____

Single _____

Common law _____

Divorced _____

Separated _____

Widow _____

Unknown _____

Study Site _____ ID# _____

Caregiver Questionnaire-Baseline

1.4 If you are the parent, does your child's other parent live with you?

Please mark only one with an X.

Yes _____

No _____

1.5 Your education.**1.5a Your highest level of education completed.**

Please mark only one with an X.

Graduate degree (PhD, MD, JD, MA) _____

Some graduate school _____

College/University degree _____

Some college _____

High school diploma/GED _____

Grade 10-11 _____

Grade 7-9 _____

Grade 1-6 _____

Unknown _____

1.5b How many years of schooling have you completed? _____ years**1.6 What is your current occupation(s)? Please write in your response(s) below.**

Study Site _____ ID# _____

Caregiver Questionnaire-Baseline

2. YOUR BELIEFS ABOUT CHILDREN'S TEETH AND DENTAL CARE

Parents have different beliefs about children's teeth and getting dental care. *Please tell us how much you agree or disagree with the following statements by circling the number that best fits your response.*

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
2a. Most children eventually develop dental cavities.	1	2	3	4	5
2b. Cavities in baby teeth don't matter since they fall out anyway.	1	2	3	4	5
2c. I don't know how to get my child to the dentist to have his/her cavities fixed.	1	2	3	4	5
2d. If I took my child to the dentist, it would not make any difference whether or not he/she developed cavities.	1	2	3	4	5
2e. I intend to take my child to the dentist <u>at least once a year</u> .	1	2	3	4	5
2f. I cannot make my child go to the dentist.	1	2	3	4	5
2g. The dentist is the best person to prevent cavities in my child.	1	2	3	4	5
2h. I don't know how to brush my child's teeth properly.	1	2	3	4	5
2i. If I helped my child brush every day, it would not make any difference whether or not he/she developed cavities.	1	2	3	4	5
2j. I intend to brush my child's teeth for him/her <u>twice a day</u> .	1	2	3	4	5
2k. I cannot make my child brush his/her teeth <u>twice daily</u> .	1	2	3	4	5

Study Site _____ ID# _____

Caregiver Questionnaire-Baseline

3. YOUR FEELINGS ABOUT VISITING THE DENTIST

The following questions are about how you would feel at the dentist. Please tell us how anxious you would feel in each of the following situations by circling the number that best fits your response.

How would you feel if you...	Extremely Anxious	Very Anxious	Fairly Anxious	Slightly Anxious	Not Anxious
3a. went to the dentist for TREATMENT TOMORROW?	1	2	3	4	5
3b. were sitting in the WAITING ROOM (waiting for treatment)?	1	2	3	4	5
3c. were about to have a TOOTH DRILLED?	1	2	3	4	5
3d. were about to have your TEETH SCALED AND POLISHED?	1	2	3	4	5
3e. were about to have a LOCAL ANESTHETIC INJECTION in your gum?	1	2	3	4	5

4. TAKING YOUR CHILD TO THE DENTIST

4a. The following questions are about taking your child to the dentist for any reason. Please circle the number that best fits your response.

	Strongly Disagree	Disagree	Neither disagree nor agree	Agree	Strongly Agree
4a1. <u>I want</u> to take my child to the dentist.	1	2	3	4	5
4a2. <u>I plan</u> to take my child to the dentist.	1	2	3	4	5

Study Site _____ ID# _____

Caregiver Questionnaire-Baseline

4b. The following questions are about how you would feel about taking your child to the dentist for preventive care (checkups, cleanings, topical fluoride) and dental treatments (fixing cavities). Please tell us how you feel by circling the number that best fits your response.



My feelings about the dentist will get in the way of taking my child to the dentist for...	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
4b1. preventive care.	1	2	3	4	5
4b2. dental treatments.	1	2	3	4	5

4c.– 4d. The following questions are about what others think about taking your child to the dentist for preventive care and dental treatments. Please tell us how you feel by circling the number that best fits your response.

People important to me ...	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
4c1. think that I should take <u>my</u> child to the dentist <u>at least once</u> a year.	1	2	3	4	5
4c2. would approve if I were to take <u>my</u> child to the dentist <u>at least once</u> a year.	1	2	3	4	5
4c3. take <u>their</u> child to the dentist <u>at least once</u> a year.	1	2	3	4	5
4d1. think that I should take <u>my</u> child to the dentist when a tooth problem is found.	1	2	3	4	5
4d2. would approve if I were to take <u>my</u> child to the dentist when a tooth problem is found.	1	2	3	4	5
4d3. take <u>their</u> child to the dentist when a tooth problem is found.	1	2	3	4	5

Study Site _____ ID# _____

Caregiver Questionnaire-Baseline

4e. Sometimes parents delay their child's dental care when other things get in the way. How likely are you to take your child to the dentist when the following happen to you? Please circle the number that best fits your response.

How likely are you to take your child to the dentist when you are ...	Very Likely	Moderately Likely	Somewhat Likely	Not At All Likely
4e1. under a lot of stress	1	2	3	4
4e2. depressed	1	2	3	4
4e3. anxious	1	2	3	4
4e4. feeling like you do not have the time (too busy)	1	2	3	4
4e5. tired	1	2	3	4
4e6. worrying about other things in your life	1	2	3	4
4e7. bothered by your crying child	1	2	3	4
4e8. bothered because your child will not stay still for the dentist to examine him/her	1	2	3	4
4e9. told by your child that he/she does not feel like going to the dentist	1	2	3	4

Study Site _____ ID# _____

Caregiver Questionnaire-Baseline

**5. YOUR FEELINGS AND THOUGHTS DURING THE LAST MONTH****For each item below, please circle how often you felt or thought that way in the last month.**

	Very Often	Fairly Often	Sometimes	Almost Never	Never
5a. <i>In the last month</i> , how often have you felt that you were unable to control the important things in your life?	0	1	2	3	4
5b. <i>In the last month</i> , how often have you felt confident about your ability to handle your personal problems?	0	1	2	3	4
5c. <i>In the last month</i> , how often have you felt that things were going your way?	0	1	2	3	4
5d. <i>In the last month</i> , how often have you felt difficulties were piling up so high that you could not overcome them?	0	1	2	3	4

6. YOUR READING HABITS**The following questions are about the materials you read. Please circle how often you do the following.**

	Very Often	Fairly Often	Sometimes	Almost Never	Never
6a. Do you ever read books on your own?	0	1	2	3	4
6b. How often do you have someone help you read health-related materials?	0	1	2	3	4
6c. How confident are you filling out medical/dental forms by yourself?	0	1	2	3	4
6d. How often do you have problems learning about your medical or dental condition because of reading difficulty?	0	1	2	3	4

Study Site _____ ID# _____

Caregiver Questionnaire-Baseline

7. YOUR ORAL HEALTH BEHAVIOR*Please circle the letter of the response that best fits you.***7.1 Do you have a dentist to go to if you need dental care?**

- a) Yes
- b) No

7.2 How long has it been since you last visited a dentist or a dental clinic for any reason?

- a) 6 months or less
- b) More than 6 months but not more than 1 year (between 6 months and 1 year)
- c) Within the past two years (between 1 and 2 years ago)
- d) Within the past five years (between 2 and 5 years ago)
- e) More than 5 years ago
- f) Never
- g) Don't know

7.3 How often do you see a dentist or dental hygienist?

- a) At least once a year
- b) Every 2 years
- c) Less often than every 2 years
- d) Whenever needed, no regular schedule
- e) Other, please specify _____
- f) Never or do not go anymore
- g) Don't know

7.4 What was the main reason for your last visit for dental care?

- a) Went for check-up, exam, or cleaning
- b) Something was wrong, bothersome, or hurting
- c) Went back for treatment that dentist discovered at an earlier check-up/exam
- d) Other, please specify _____
- e) Don't know

Study Site _____ ID# _____

Caregiver Questionnaire-Baseline

7.5. PLEASE ANSWER ONLY IF YOU HAVE NOT SEEN A DENTIST WITHIN THE PAST 2 YEARS (if you answered d, e, or f to Question 7.2):**If you did not go to a dental clinic in the past 2 years, is it because...****(Please circle all that apply)**

- a) I had no dental problems, no need to go.
- b) I thought the dental problem would go away.
- c) I was too busy or unable to take time off from work.
- d) Lack of transportation.
- e) Dental treatment is very expensive.
- f) I do not have dental insurance or Medicaid.
- g) I was unable to make an appointment.
- h) I was unable to leave my child/children to go to the appointment.
- i) Other reason, please specify _____

7.6. During the last month were you covered by a government plan such as Medicaid?

- a) Yes
- b) No
- c) Don't know

7.7. During the last month were you covered by a dental insurance plan obtained privately or through a current or former employer or union? Include membership in a health maintenance organization (HMO).

- a) Yes
- b) No
- c) Don't know

7.8. How often do you think costs for dental care are reasonable?

- a) Never
- b) Sometimes
- c) Usually
- d) Always
- e) Don't know

Study Site _____ ID# _____

Caregiver Questionnaire-Baseline

7.9. How often do you brush your teeth?

- a) More than two times a day
- b) Two times a day
- c) One time a day
- d) One time a week
- e) Never

7.10. How often do you floss your teeth?

- a) More than two times a day
- b) Two times a day
- c) One time a day
- d) One time a week
- e) Few times a week
- f) Never

7.11. Have you had toothaches or cavities in the past 12 months?

- a) Yes
- b) No

7.12. Have you had bleeding gums or have you been told you had a gum disease in the past 12 months?

- a) Yes
- b) No

7.13. How would you describe the health of your mouth and teeth?

- a) Excellent
- b) Very good
- c) Good
- d) Fair
- e) Poor

Study Site _____ ID# _____

Caregiver Questionnaire-Baseline

7.14. Have you missed work or school in the past 12 months because of dental problems?

- a) Yes → Please answer Question 7.14a
- b) No

7.14a. How many hours of work or school did you miss? _____ hours**7.15. Did you see a dentist regularly (1-2 times a year) when you were a child between the ages of 7-12?**

- a) Yes
- b) No
- c) Don't know

7.16. Did your parent(s) watch your toothbrushing when you were a child between the ages of 7-12?

- a) Yes
- b) No
- c) Don't know

7.17. Did your parent(s) talk about the importance of dental care when you were a child between the ages of 7-12?

- a) Yes
- b) No
- c) Don't know

Study Site _____ ID# _____

Caregiver Questionnaire-Baseline

8. YOUR CHILD'S ORAL HEALTH BEHAVIOR

Please circle the letter of the response that best fits your child.

8.1. During an *ideal week*, how often does your child brush his/her teeth?

- a) Doesn't brush his/her teeth
- b) Less than once a week
- c) Once or twice a week
- d) About every other day
- e) Almost every day
- f) Once a day
- g) Twice a day
- h) More than twice a day
- i) Don't know

8.2. Has your child ever been seen by a dentist?

- a) Yes → Please answer Question 8.2a
- b) No
- c) Don't know

8.2a About how old was your child at this first visit? _____**8.3. During the *past 12 months*, how many times did your child see a doctor, nurse or other health care provider for preventive medical care such as a physical exam or well-child check-up? (Please DO NOT include visits when your child was sick or when something was bothering them)**

Number of times: _____

8.4. During the *past 12 months*, how many times did your child see a dentist for preventive dental care such as check-ups, dental cleanings, and fluoride? (Please DO NOT include visits when your child was in pain or when something was bothering them)

Number of times: _____

Study Site _____ ID# _____

Caregiver Questionnaire-Baseline

8.4a. If you answered at least 1 time for Question 8.4, was this place a:

- a) Dentist's office
- b) Emergency department
- c) Hospital
- d) Clinic
- e) Other, please write here _____

8.5. During the past 12 months, did your child receive all the routine preventive dental care he/she needed (e.g. check-ups, dental cleanings, and fluoride)?

- a) Yes
- b) No → Please answer Question 8.5a
- c) Don't know

8.5a. Why did your child NOT get all the preventive dental care he/she needed?

- a) My child had no dental problems, no need to go.
- b) I thought my child's dental problem would go away.
- c) I was too busy, unable to take time off from work to take my child.
- d) Lack of transportation.
- e) Preventive dental care is very expensive.
- f) My child does not have dental insurance or Medicaid.
- g) I was unable to make an appointment for my child.
- h) I was unable to leave my other child(ren) to go to the appointment.
- i) Other, please specify _____

8.6. During the last month did your child have any kind of dental coverage, such as a private plan, preferred plan (like an HMO), or government plan (like Medicaid)?

- a) Yes → Please answer Question 8.6a
- b) No
- c) Don't know

8.6a. Was your child insured by Medicaid or the State Children's Health Insurance Program (S-CHIP)?

- a) Yes
- b) No
- c) Don't know

Study Site _____ ID# _____

Caregiver Questionnaire-Baseline

8.7. Is there a place your child usually goes when he/she needs treatment for a dental problem, like a cavity or tooth pain?

- a) Yes → Please answer Question 8.7a
- b) No
- c) Don't know

8.7a. Is this place a:

- a) Dentist's office
- b) Emergency department
- c) Hospital
- d) Clinic
- e) Other, please specify _____

8.8. Sometimes people have trouble getting all the dental treatment they need. During the *past 12 months*, was there any time when your child needed dental care but it was delayed or not received?

- a) Yes → Please answer Questions 8.8a and 8.8b
- b) No
- c) Don't know

Please skip to Question 8.9

8.8a. What type of treatment was delayed or not received after a problem had been found by a dental provider? Please circle all that apply.

- a) Filling
- b) Extraction [having a tooth pulled]
- c) Crown / metal cap
- d) Pulp therapy [baby root canal]
- e) Gum disease
- f) Other, please specify _____
- g) Don't remember

Study Site _____ ID# _____

Caregiver Questionnaire-Baseline

8.8b. Why did your child NOT get all the dental care that he/she needed? Here are some common reasons from other parents — please circle all that apply.

- a) The cost is too much.
- b) My child does not have dental insurance or Medicaid.
- c) My family has a problem with our health care plan.
- d) I cannot find a dentist who accepts my child's insurance.
- e) There are no available dentists in my area. / I have transportation problems.
- f) It is difficult to get convenient appointment times. / My child could not get an appointment.
- g) The dentist did not know how to treat or provide care for my child.
- h) I was dissatisfied with the dentist.
- i) I did not know where to take my child for treatment.
- j) My child refused to go.
- k) My child's treatment is ongoing.
- l) My child needed a referral and we could not get one.
- m) Other, please specify _____

8.9. During the past 12 months, did you, a doctor, or a dentist think your child needed to see a dental specialist (for example, a pediatric dentist)?

- a) Yes → Please answer Question 8.9a
- b) No
- c) Don't know

8.9a. During the past 12 months, how much of a problem—if any—was it to get the care from the specialist that your child needed?

- a) Big problem
- b) Small problem
- c) Not a problem
- d) Don't know

8.10. A personal dentist is a health professional who knows your child well and is familiar with your child's dental health history. Do you have one or more persons that you think of as your child's personal dentist?

- a) Yes, 1 person
- b) Yes, more than 1 person
- c) No

THANK YOU!

16

Site: _____ ID# _____

Family Access to Dentist Study

**Your Feelings
About Cavities**

January 29, 2015

2-week Follow-up

Site: _____ ID# _____

Instructions:

We are interested in your views about your child's cavities (tooth decay). Please indicate how much you agree or disagree with the following statements about cavities by circling one of the following responses for each question: *strongly agree (1), agree (2), neither agree nor disagree (3), disagree (4), strongly disagree (5)*.

1. *Please tell us whether you believe each of the following is a symptom related to dental cavities in children:*

1a. Tooth pain
 1b. Tooth sensitivity to hot or cold
 1c. Hole in tooth
 1d. Dark or white spot on tooth
 1e. Swelling in face or gums (including a gum boil or abscess)

Yes	No

Please circle the number of the best answer for each question. If your child has not had cavities, please respond how you would if they did.

About your child:

Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
----------------	-------	----------------------------	----------	-------------------

2. Cavities in my child is a serious illness.
 3. Cavities in my child has had a big effect on his/her life.
 4. Cavities in my child has had a big effect on how he/she smiles.
 5. Cavities in my child has had a big effect on his/her behavior at home.
 6. Cavities in my child has had a big effect on his/her school work.
 7. Cavities in my child has had a big effect on his/her self-worth.
 8. Cavities in my child is disabling.

1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5

Site: _____ ID#_____

About you:

9. Cavities in my child has a big impact on my life.

10. I cannot easily live with my child's cavities.

11. Cavities in my child has a big effect on how others see me.

12. Cavities in my child has caused money problems for me.

13. Cavities in my child has a big effect on my self-worth.

Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
----------------	-------	----------------------------	----------	-------------------

1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5

About your child:

14. There is a lot that can be done to improve the cavities in my child.

15. My child's treatment will help make his/her cavities better.

16. Improvement in my child's cavities is not due to chance or fate.

17. What my child does decides if his/her cavities get better or worse.

Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
----------------	-------	----------------------------	----------	-------------------

1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5

About you:

18. There is a lot I can do to control my child's cavity symptoms.

19. What I do decides if my child's cavities get better or worse.

20. There is a lot I can do to stop my child's cavities once they start.

21. There is a lot I can do to prevent cavities in my child.

Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
----------------	-------	----------------------------	----------	-------------------

1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5

Site: _____ ID# _____

<i>About your child:</i>	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
	1	2	3	4	5
22. My child's cavities will not get better over time.					
23. Cavities in my child are likely to be long-lasting rather than short-term.					
<i>About your child:</i>	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
	1	2	3	4	5
24. Cavities in my child may change from time to time.					
25. There will be times when my child's cavity symptoms get worse and times when they get better.					
<i>About you:</i>	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
	1	2	3	4	5
26. I have a clear understanding of my child's cavities.					
27. My child's cavity symptoms are not confusing to me.					
<i>About you:</i>	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
	1	2	3	4	5
28. I get really sad and upset when I think about my child suffering from cavities.					
29. Seeing my child with cavities worries <u>me</u> .					
30. Seeing my child with cavities makes <u>me</u> feel angry.					
31. Seeing my child with cavities can make <u>me</u> feel helpless.					

Site: _____ ID# _____

32. Causes of children's cavities:

We would like to know what you think causes cavities in children. There is no correct answer. We are interested in your own ideas about children's cavities rather than what others (including doctors or family) may have told you. Below is a list of possible causes.

Please tell us how much you agree or disagree with each cause by circling the number that best fits your answer: **strongly agree (1), agree (2), neither agree nor disagree (3), disagree (4), strongly disagree (5).**

<i>Please circle the number of the best answer</i>	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
	1	2	3	4	5
32a. Stress or worry can cause cavities in a child	1	2	3	4	5
32b. Cavities runs in families	1	2	3	4	5
32c. A germ or virus can cause cavities in a child	1	2	3	4	5
32d. Diet or eating habits can cause cavities in a child	1	2	3	4	5
32e. Chance or bad luck can cause cavities in a child	1	2	3	4	5
32f. Poor dental care can cause cavities in a child	1	2	3	4	5
32g. Something a parent/caregiver does can cause cavities in a child	1	2	3	4	5
32h. A parent/caregiver's negative thoughts can cause cavities in a child	1	2	3	4	5
32i. Family problems or a parent/caregiver's worries can cause cavities in a child	1	2	3	4	5
32j. A parent/caregiver's feelings (feeling down, anxious) can cause cavities in a child	1	2	3	4	5
32k. A child's lack of ability to fight off infections can cause cavities	1	2	3	4	5

Site: _____ ID#_____

33. Please list in order the three most important things that you believe cause cavities in children. You may use any of the items from the previous question or you may have other ideas of your own.

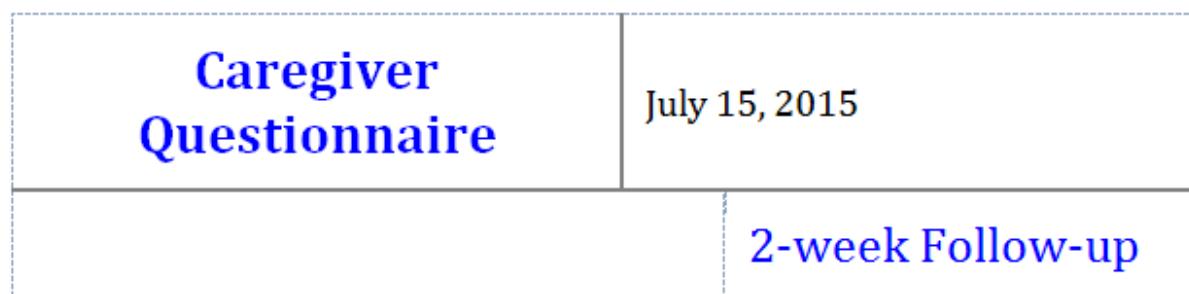
The most important causes for me are:

1st _____

2nd _____

3rd _____

Family Access to Dentist Study



Study Site: _____ ID#: _____

Caregiver Questionnaire-2-week Follow-up

1. TAKING YOUR CHILD TO THE DENTIST**1.1 Did your child visit the dentist after the school dental screening?**

- a) Yes → Please GO TO Question 1.2
- b) No, but I have made an appointment with the dentist → Please SKIP TO Question 1.5
- c) No, and I have not made an appointment with the dentist → Please SKIP TO Question 1.6

If you answered YES to Question 1.1 above, please answer the following questions:

1.2 What is the name of the dental clinic / dentist where you took your child?

1.3 Did you take the referral letter (from the school dental screening) with you to the dentist?

- a) Yes
- b) No

1.4 Did your child complete the needed dental treatment?

- a) Yes

If YES, how many visits were needed to complete your child's dental treatment? _____

- b) No, but my child has a follow-up appointment

If NO, when is the follow-up appointment? _____

- c) No

If NO, why did your child not complete dental treatment? _____

- d) Don't know

Please GO TO Question 1.5

Study Site: _____ ID#: _____

Caregiver Questionnaire-2-week Follow-up

If you answered YES or NO, but I have made an appointment to Question 1.1 above, please answer the following question:

1.5 Were there any items below that helped you decide to take your child to the dentist/make an appointment with the dentist?

Please circle all that apply.

- a) The referral letter
- b) Information on myths and facts of children's dental health
- c) Helpful hints on getting my child dental care
- d) Information on making a dental appointment for my child
- e) Knowing about the dentists in my area
- f) The outreach individual at my child's school
- g) Don't know

THANK YOU!

Study Site: _____ ID#: _____

Caregiver Questionnaire-2-week Follow-up



If you answered NO, and I have not made an appointment to Question 1.1 above, please answer the following questions:

1.6. The following questions are about taking your child to the dentist.

Please circle the number that best fits your response.

	Strongly Disagree	Disagree	Neither disagree nor agree	Agree	Strongly Agree
1.6a <u>I want</u> to take my child to the dentist.	1	2	3	4	5
1.6b <u>I plan</u> to take my child to the dentist.	1	2	3	4	5

1.7. Why has your child NOT been able to visit the dentist since the school dental screening? Here are some common reasons from other parents – *please circle all that apply*.

- a) The cost is too much.
- b) My child does not have dental insurance or Medicaid.
- c) My family has a problem with our health care plan.
- d) I cannot find a dentist who accepts my child's insurance.
- e) There are no available dentists in my area / I have transportation problems.
- f) It is difficult to get convenient appointment times / My child could not get an appointment.
- g) The dentist did not know how to treat or provide care for my child.
- h) I was dissatisfied with the dentist.
- i) I did not know where to take my child for treatment.
- j) My child refused to go.
- k) My child's treatment is ongoing.
- l) Other, please specify _____

THANK YOU!

Site: _____ ID#: _____

Family Access to Dentist Study

**Your Feelings
About Cavities**

January 29, 2015

Final Follow-up

Site: _____ ID#_____

Instructions:

We are interested in your views about your child's cavities (tooth decay). Please indicate how much you agree or disagree with the following statements about cavities by circling one of the following responses for each question: **strongly agree (1), agree (2), neither agree nor disagree (3), disagree (4), strongly disagree (5).**

1. *Please tell us whether you believe each of the following is a symptom related to dental cavities in children:*

1a. Tooth pain	Yes	No
1b. Tooth sensitivity to hot or cold	Yes	No
1c. Hole in tooth	Yes	No
1d. Dark or white spot on tooth	Yes	No
1e. Swelling in face or gums (including a gum boil or abscess)	Yes	No

Yes	No
Yes	No

Please circle the number of the best answer for each question. If your child has not had cavities, please respond how you would if they did.

About your child:

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
2. Cavities in my child is a serious illness.	1	2	3	4	5
3. Cavities in my child has had a big effect on <u>his/her</u> life.	1	2	3	4	5
4. Cavities in my child has had a big effect on how <u>he/she</u> smiles.	1	2	3	4	5
5. Cavities in my child has had a big effect on <u>his/her</u> behavior at home.	1	2	3	4	5
6. Cavities in my child has had a big effect on <u>his/her</u> school work.	1	2	3	4	5
7. Cavities in my child has had a big effect on <u>his/her</u> self-worth.	1	2	3	4	5
8. Cavities in my child is disabling.	1	2	3	4	5

Site: _____ ID# _____

About you:	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
	1	2	3	4	5
9. Cavities in my child has a big impact on <u>my</u> life.	1	2	3	4	5
10. I cannot easily live with <u>my</u> child's cavities.	1	2	3	4	5
11. Cavities in my child has a big effect on how others see <u>me</u> .	1	2	3	4	5
12. Cavities in my child has caused money problems <u>for me</u> .	1	2	3	4	5
13. Cavities in my child has a big effect on <u>my</u> self-worth.	1	2	3	4	5

About your child:	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
	1	2	3	4	5
14. There is a lot that can be done to improve the cavities in <u>my child</u> .	1	2	3	4	5
15. <u>My child's</u> treatment will help make his/her cavities better.	1	2	3	4	5
16. Improvement in <u>my child's</u> cavities is not due to chance or fate.	1	2	3	4	5
17. <u>What my child</u> does decides if his/her cavities get better or worse.	1	2	3	4	5

About you:	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
	1	2	3	4	5
18. There is a lot <u>I can</u> do to control my child's cavity symptoms.	1	2	3	4	5
19. <u>What I do</u> decides if my child's cavities get better or worse.	1	2	3	4	5
20. There is a lot <u>I can</u> do to stop my child's cavities once they start.	1	2	3	4	5
21. There is a lot <u>I can</u> do to prevent cavities in my child.	1	2	3	4	5

Site: _____ ID#_____

About your child:

22. My child's cavities will not get better over time.

23. Cavities in my child are likely to be long-lasting rather than short-term.

Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
----------------	-------	----------------------------	----------	-------------------

1	2	3	4	5
1	2	3	4	5

About your child:

24. Cavities in my child may change from time to time.

25. There will be times when my child's cavity symptoms get worse and times when they get better.

Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
----------------	-------	----------------------------	----------	-------------------

1	2	3	4	5
1	2	3	4	5

About you:

26. I have a clear understanding of my child's cavities.

27. My child's cavity symptoms are not confusing to me.

Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
----------------	-------	----------------------------	----------	-------------------

1	2	3	4	5
1	2	3	4	5

About you:

28. I get really sad and upset when I think about my child suffering from cavities.

29. Seeing my child with cavities worries me.

30. Seeing my child with cavities makes me feel angry.

31. Seeing my child with cavities can make me feel helpless.

Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
----------------	-------	----------------------------	----------	-------------------

1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5

Site: _____ ID#: _____

32. Causes of children's cavities:

We would like to know what you think causes cavities in children. There is no correct answer. We are interested in your own ideas about children's cavities rather than what others (including doctors or family) may have told you. Below is a list of possible causes.

Please tell us how much you agree or disagree with each cause by circling the number that best fits your answer: **strongly agree (1), agree (2), neither agree nor disagree (3), disagree (4), strongly disagree (5).**

<i>Please circle the number of the best answer</i>	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
	1	2	3	4	5
32a. Stress or worry can cause cavities in a child					
32b. Cavities runs in families					
32c. A germ or virus can cause cavities in a child					
32d. Diet or eating habits can cause cavities in a child					
32e. Chance or bad luck can cause cavities in a child					
32f. Poor dental care can cause cavities in a child					
32g. Something a parent/caregiver does can cause cavities in a child					
32h. A parent/caregiver's negative thoughts can cause cavities in a child					
32i. Family problems or a parent/caregiver's worries can cause cavities in a child					
32j. A parent/caregiver's feelings (feeling down, anxious) can cause cavities in a child					
32k. A child's lack of ability to fight off infections can cause cavities					

Site: _____ ID#: _____

33. Please list in order the three most important things that you believe cause cavities in children. You may use any of the items from the previous question or you may have other ideas of your own.

The most important causes for me are:

1st _____

2nd _____

3rd _____

Family Access to Dentist Study

Caregiver Questionnaire	June 29, 2015
	Final Follow-up

1

Study Site: _____ ID#: _____

Caregiver Questionnaire-Final Follow-up

Date of Interview: _____

Interviewer's initials: _____

month day year

1. BACKGROUND INFORMATION**1.1 Your marital status.** Please mark only one with an X.

Married	_____	Divorced	_____
Single	_____	Separated	_____
Common law	_____	Widow	_____
Unknown	_____		

1.2 If you are the parent, does your child's other parent live with you?

Yes	_____
No	_____

1.3 Your education.**1.3a How many years of schooling have you completed?** _____ years**1.3b Your highest level of education completed.** Please mark only one with an X.

Graduate degree (PhD, MD, JD, MA)	_____
Some graduate school	_____
College/University degree	_____
Some college	_____
High school diploma/GED	_____
Grade 10-11	_____
Grade 7-9	_____
Grade 1-6	_____
Unknown	_____

1.4 What is your current occupation(s)? Please write in your response(s) below.

2

Study Site: _____ ID#: _____

Caregiver Questionnaire-Final Follow-up

2. YOUR BELIEFS ABOUT CHILDREN'S TEETH AND DENTAL CARE

Parents have different beliefs about children's teeth and getting dental care. Please tell us how much you agree or disagree with the following statements by circling the number that best fits your response.

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
2a. Most children eventually develop dental cavities.	1	2	3	4	5
2b. Cavities in baby teeth don't matter since they fall out anyway.	1	2	3	4	5
2c. I don't know how to get my child to the dentist to have his/her cavities fixed.	1	2	3	4	5
2d. If I took my child to the dentist, it would not make any difference whether or not he/she developed cavities.	1	2	3	4	5
2e. I intend to take my child to the dentist <u>at least once</u> a year.	1	2	3	4	5
2f. I cannot make my child go to the dentist.	1	2	3	4	5
2g. The dentist is the best person to prevent cavities in my child.	1	2	3	4	5
2h. I don't know how to brush my child's teeth properly.	1	2	3	4	5
2i. If I helped my child brush every day, it would not make any difference whether or not he/she developed cavities.	1	2	3	4	5
2j. I intend to brush my child's teeth for him/her <u>twice</u> a day.	1	2	3	4	5
2k. I cannot make my child brush his/her teeth <u>twice</u> daily.	1	2	3	4	5

Study Site: _____ ID#: _____

Caregiver Questionnaire-Final Follow-up

3. TAKING YOUR CHILD TO THE DENTIST

3a.-3b. The following questions are about what others think about taking your child to the dentist for preventive care and dental treatments. Please tell us how you feel by circling the number that best fits your response.



People important to me ...	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
3a1. think that I should take <u>my</u> child to the dentist <u>at least once a year</u> .	1	2	3	4	5
3a2. would approve if I were to take <u>my</u> child to the dentist <u>at least once a year</u> .	1	2	3	4	5
3a3. take <u>their</u> child to the dentist <u>at least once a year</u> .	1	2	3	4	5
<hr/>					
3b1. think that I should take <u>my</u> child to the dentist when a tooth problem is found.	1	2	3	4	5
3b2. would approve if I were to take <u>my</u> child to the dentist when a tooth problem is found.	1	2	3	4	5
3b3. take <u>their</u> child to the dentist when a tooth problem is found.	1	2	3	4	5

□

Study Site: _____ ID#: _____

Caregiver Questionnaire-Final Follow-up

3c. Sometimes parents delay their child's dental care when other things get in the way. How likely are you to take your child to the dentist when the following happen to you? *Please circle the number that best fits your response.*

How likely are you to take your child to the dentist when you are ...	Very Likely	Moderately Likely	Somewhat Likely	Not At All Likely
3c1. under a lot of stress	1	2	3	4
3c2. depressed	1	2	3	4
3c3. anxious	1	2	3	4
3c4. feeling like you do not have the time (too busy)	1	2	3	4
3c5. tired	1	2	3	4
3c6. worrying about other things in your life	1	2	3	4
3c7. bothered by your crying child	1	2	3	4
3c8. bothered because your child will not stay still for the dentist to examine him/her	1	2	3	4
3c9. told by your child that he/she does not feel like going to the dentist	1	2	3	4

Study Site: _____ ID#: _____

Caregiver Questionnaire-Final Follow-up

4. YOUR CHILD'S ORAL HEALTH BEHAVIOR

Please circle the letter of the response that best fits your child.

4.1 During an ideal week, how often does your child brush his/her teeth?

- a) Doesn't brush his/herteeth
- b) Less than once a week
- c) Once or twice a week
- d) About every other day
- e) Almost every day
- f) Once a day
- g) Twice a day
- h) More than twice a day
- i) Don't know

4.2 Since the start of this school year, did your child have any kind of dental coverage, such as a private plan, preferred plan (like an HMO), or government plan (like Medicaid)?

- a) Yes → Please answer Question 4.2a
- b) No
- c) Don't know

4.2a Was your child insured by Medicaid or the State Children's Health Insurance Program (S-CHIP)?

- a) Yes
- b) No
- c) Don't know

4.3 Is there a place your child usually goes when he/she needs treatment for a dental problem, like a cavity or tooth pain?

- a) Yes → Please answer Question 4.3a
- b) No
- c) Don't know

Study Site: _____ ID#: _____

Caregiver Questionnaire-Final Follow-up

4.3a If you answered YES, is this place a:

- a) Dentist's office
- b) Emergency department
- c) Hospital
- d) Clinic
- e) Other, please specify _____

4.4 Sometimes people have trouble getting all the dental treatment they need. Since the start of this school year, was there any time when your child needed dental care but it was delayed or not received?

- a) Yes → Please answer Question 4.4a
- b) No
- c) Don't know } Please skip to Question 4.5

4.4a What type of treatment was delayed or not received after a problem had been found by a dental provider? Please circle all that apply.

- a) Filling
- b) Extraction [having a tooth pulled]
- c) Crown / metal cap
- d) Pulp therapy [baby root canal]
- e) Gum disease
- f) Other, please specify _____
- g) Don't remember

4.5 Did your child visit the dentist after the school dental screening?

- a) Yes → Go to Question 5A
- b) No → Go to Question 5B

Study Site: _____ ID#: _____

Caregiver Questionnaire-Final Follow-up

5A. YOUR THOUGHTS ABOUT THE STUDY

If you answered YES to Question 4.5 (your child visited the dentist), please answer the following questions:

5.1. What is the name of the dental clinic / dentist where you took your child?

5.2. What month after the dental screening did you take your child to the dentist?

5.3. Did you take the referral letter (from the school dental screening) with you to the dentist?

- a) Yes
- b) No

5.4. Did your child complete the needed dental treatment?

- a) Yes

If YES, how many visits were needed to complete your child's dental treatment? _____

- b) No, but my child has a follow-up appointment

If NO, when is the follow-up appointment? _____

- c) No

If NO, why did your child not complete dental treatment? _____

- d) Don't know

Please GO TO Question 5.5

Study Site: _____ ID#: _____

Caregiver Questionnaire-Final Follow-up

5.5 Were there any items below that helped you get your child to the dentist?*Please circle all that apply.*

- a) The referral letter
- b) Information on myths and facts of children's dental health
- c) Helpful hints on getting my child dental care
- d) Information on making a dental appointment for my child
- e) Knowing about the dentists in my area
- f) The outreach individual at my child's school
- g) Don't know

5.6 Did you find the referral letter easy to understand?

- a) Yes
- b) No

5.7 Which study group do you think you and your child were in?

- a) Standard letter
- b) Improved letter
- c) Improved letter with materials
- d) Don't know

THANK YOU!

Study Site: _____ ID#: _____

Caregiver Questionnaire-Final Follow-up

5B. YOUR THOUGHTS ABOUT THE STUDY

*If you answered **NO** to Question 4.5 (your child did not visit the dentist), please answer the following questions:*

5.1. The following questions are about taking your child to the dentist. Please circle the number that best fits your response.

	Strongly Disagree	Disagree	Neither disagree nor agree	Agree	Strongly Agree
5.1a <u>I want to</u> take my child to the dentist.	1	2	3	4	5
5.1b <u>I plan to</u> take my child to the dentist.	1	2	3	4	5

5.2. Why has your child NOT been able to visit the dentist since the school dental screening? Here are some common reasons from other parents — please circle all that apply.

- a) The cost is too much.
- b) My child does not have dental insurance or Medicaid.
- c) My family has a problem with our health care plan.
- d) I cannot find a dentist who accepts my child's insurance.
- e) There are no available dentists in my area / I have transportation problems.
- f) It is difficult to get convenient appointment times / My child could not get an appointment.
- g) The dentist did not know how to treat or provide care for my child.
- h) I was dissatisfied with the dentist.
- i) I did not know where to take my child for treatment.
- j) My child refused to go.
- k) My child's treatment is ongoing.
- l) Other, please specify _____

Study Site: _____ ID#: _____

Caregiver Questionnaire-Final Follow-up

5.3 Were there any items below that would have helped you get your child to the dentist?*Please circle all that apply.*

- a) The referral letter
- b) Information on myths and facts of children's dental health
- c) Helpful hints on getting my child dental care
- d) Information on making a dental appointment for my child
- e) Knowing about the dentists in my area
- f) The outreach individual at my child's school
- g) Don't know

5.4 Did you find the referral letter easy to understand?

- a) Yes
- b) No

5.5 Which study group do you think you and your child were in?

- c) Standard letter
- d) Improved letter
- e) Improved letter with materials
- f) Don't know

THANK YOU!

Site: _____ ID# _____

Estudio de Acceso de la Familia al Dentista

**Sus Sentimientos
Acerca de la Caries**

29 de Enero de 2015

**Punto de
Referencia IPQ-RD**

Site: _____ ID# _____

Instrucciones:

Nosotros estamos interesados en su punto de vista acerca de las caries en su niño/a (caries en el diente). Por favor indique cuanto usted está de acuerdo o desacuerdo con las siguientes oraciones acerca de la caries al hacer un círculo en las siguientes respuestas de cada pregunta: *totalmente de acuerdo (1), de acuerdo (2), ni de acuerdo ni en desacuerdo (3), desacuerdo (4), en total desacuerdo (5)*.

Por favor diganos si cree que cada una de las siguientes es un síntoma relacionado a caries dentales en los niños/as:

1a.	Dolor de diente	Yes	No
1b.	Dientes sensibles a lo caliente o helado	Yes	No
1c.	Hoyo en el diente	Yes	No
1d.	Manchas blancas o oscuras en los dientes	Yes	No
1e.	Inflamación en la cara o encillas (incluyendo una postemilla o absceso)	Yes	No

Por favor haga un círculo en el número de la mejor respuesta para cada pregunta. Si su niño/a no ha tenido caries, por favor responda como se sentiría si ellos tuvieran.

Acerca de su niño/a:	Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
2. Las caries en mi niño/a es una enfermedad seria.	1	2	3	4	5
3. Las caries en mi niño/a han tenido un gran efecto en su vida.	1	2	3	4	5
4. Las caries en mi niño/a han tenido un gran efecto en como <u>el/ella</u> sonríe.	1	2	3	4	5
5. Las caries en mi niño/a han tenido un gran efecto en como <u>el/ella</u> se comporta en la casa.	1	2	3	4	5
6. Las caries en mi niño/a han tenido un gran efecto en como hace <u>el/ella</u> su trabajo en la escuela.	1	2	3	4	5
7. Las caries en mi niño/a han tenido un gran efecto en como se siente acerca de <u>el/ella</u> misma.	1	2	3	4	5
8. Las caries en mi niño/a es una incapacidad.	1	2	3	4	5

Site: _____ ID# _____

Acerca de usted:	Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
9. Las caries en mi niño/a tienen un gran impacto en <u>mi</u> vida.	1	2	3	4	5
10. Simplemente no puedo vivir con las caries de <u>mi</u> niño/a.	1	2	3	4	5
11. Las caries en mi niño/a tienen un gran efecto en como otros <u>me</u> ven.	1	2	3	4	5
12. Las caries en mi niño/a <u>me</u> ha causado problemas de dinero.	1	2	3	4	5
13. Las caries en mi niño/a tienen un gran efecto en <u>mi</u> autoestima.	1	2	3	4	5

Acerca de su niño/a:	Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
14. Hay mucho que se puede hacer para mejorar las caries en <u>mi</u> niño/a.	1	2	3	4	5
15. El tratamiento en <u>mi</u> niño/a le ayudara a mejorar sus caries.	1	2	3	4	5
16. El mejoramiento en las caries de <u>su</u> niño/a no va a cambiar por casualidad o destino.	1	2	3	4	5
17. Lo que haga <u>mi</u> niño/a decidirá si sus caries mejoran o empeoran.	1	2	3	4	5

Acerca de usted:	Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
18. Hay mucho que <u>yo</u> <u>puedo</u> hacer para controlar los síntomas de la caries de mi niño/a.	1	2	3	4	5
19. Lo que <u>yo</u> <u>haga</u> decide si las caries mi niño/a se mejoran o empeoran.	1	2	3	4	5
20. Es mucho lo que <u>yo</u> <u>puedo</u> hacer para parar las caries de mi niño/a una vez que empiezan.	1	2	3	4	5
21. Es mucho lo que <u>yo</u> <u>puedo</u> hacer para prevenir las caries en mi niño/a.	1	2	3	4	5

Site: _____ ID# _____

Acerca de su niño/a:

	Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
--	-----------------------	------------	--------------------------------	------------	---------------------

22. Las caries de mi niño/a no se mejorarán con el tiempo.

1	2	3	4	5
---	---	---	---	---

23. Es probable que las caries en mi niño/a sean duraderas y no a corto plazo.

1	2	3	4	5
---	---	---	---	---

Acerca de su niño/a:

	Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
--	-----------------------	------------	--------------------------------	------------	---------------------

24. Las caries en mi niño/a podrían cambiar de vez en cuando.

1	2	3	4	5
---	---	---	---	---

25. Habrá momentos cuando los síntomas de las caries de mi niño/a se empeoran y tiempos cuando se mejoran.

1	2	3	4	5
---	---	---	---	---

Acerca de usted:

	Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
--	-----------------------	------------	--------------------------------	------------	---------------------

26. Tengo un claro entendimiento de las caries de mi niño/a.

1	2	3	4	5
---	---	---	---	---

27. Los síntomas de las caries de mi niño/a no son confuso para mí.

1	2	3	4	5
---	---	---	---	---

Acerca de usted:

	Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
--	-----------------------	------------	--------------------------------	------------	---------------------

28. Me pongo muy triste y molesto cuando pienso que mi niño/a está sufriendo de caries.

1	2	3	4	5
---	---	---	---	---

29. Ver a mi niño/a con caries me preocupa.

1	2	3	4	5
---	---	---	---	---

30. Ver a mi niño/a con caries me hace sentir enojado.

1	2	3	4	5
---	---	---	---	---

31. Ver a mi niño/a con caries me hace sentir impotente.

1	2	3	4	5
---	---	---	---	---

Site: _____ ID# _____

32. Causas de las caries en los niños/as:

Nosotros estamos interesados en su punto de vista acerca de las caries de su niño/a. No hay una respuesta correcta. Nosotros estamos interesados en sus propias ideas acerca de las causas de las caries de su niño/a en lugar de lo que otros (incluyendo doctores o familia) puedan haberle dicho. Abajo esta una lista de posibles causas.

Por favor Indique cuanto usted está de acuerdo o desacuerdo con cada causa haciendo un círculo al número que mejor se adapte a su respuesta: *totalmente de acuerdo (1), de acuerdo (2), ni de acuerdo ni de desacuerdo (3), desacuerdo (4), totalmente en desacuerdo (5)*.

Por favor haga un círculo en el número de la mejor respuesta

	Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
32a. La causa de la caries en mi niño/a es el estrés o preocupación.	1	2	3	4	5
32b. La caries corren en mi familia.	1	2	3	4	5
32c. Un germen o virus causó la caries de mi niño/a.	1	2	3	4	5
32d. La dieta o hábitos alimenticios causaron la caries en mi niño/a.	1	2	3	4	5
32e. Casualidad o suerte causaron las caries de mi niño/a.	1	2	3	4	5
32f. El pobre cuidado dental causó la caries de mi niño/a.	1	2	3	4	5
32g. Algo que yo hice como padre/madre causó la caries a mi niño/a.	1	2	3	4	5
32h. Mis pensamientos negativos causaron la caries de mi niño/a.	1	2	3	4	5
32i. Los problemas de familia o preocupaciones causaron la caries en mi niño/a.	1	2	3	4	5
32j. Mis sentimientos (sentime decaído, ansioso) le causó la caries a mi niño/a.	1	2	3	4	5
32k. La falta de habilidad de pelear la infección causó la caries de mi niño/a.	1	2	3	4	5

Site: _____ ID# _____

33. Por favor escriba en orden las 3 cosas más importantes que usted cree ahora causaron la caries de su niño/a. Usted puede usar cualquiera de los artículos de las preguntas anteriores o que tenga otras ideas propias.

Las causas más importantes para mí son:

1st _____

2nd _____

3rd _____

sitio del estudio _____ # de identificación _____

Cuestionario del cuidador -Referencia

Estudio de Acceso de la Familia al Dentista

**Cuestionario del
Cuidador**

29 de Junio, 2015

Punto de Referencia

sitio del estudio _____ # de identificación _____

Cuestionario del cuidador -Referencia

Fecha de la entrevista _____
Mes día año

Iniciales del entrevistador _____

1. INFORMACIÓN DE ANTECEDENTES**1.1 Su edad** _____ años**1.2 Su raza y etnicidad (origen étnico)****1.2a Su raza****1.2b Su etnicidad**

Por favor marque con una X todas las que apliquen Por favor marque solo una con una X

Blanco _____

No Hispano /Latino _____

Asiático _____

Hispano/ Latino _____

Indio Americano / Nativo de Alaska _____

Desconocido _____

Hawaiano (Nativo de las islas del
Pacifico) _____

Más de una raza _____

Desconocido _____

1.3 Su estado marital

Por favor marque solo uno con una X

Casado _____

Soltero _____

Derecho común _____

Divorciado _____

Separado _____

Viudo _____

Desconocido _____

sitio del estudio _____ # de identificación _____

Cuestionario del cuidador -Referencia

1.4 ¿Si usted es el padre o la madre, ¿está el otro parente o madre viviendo con usted?

Si _____

No _____

1.5 Su educación**1.5a. Su más alto nivel de educación completo. Por favor, marque solo uno con una X**

Título de posgrado _____

Algunos años de educación superior _____

Título de Universidad/Colegio _____

Algunos estudios de Universidad _____

Diploma de bachillerato /
examen de desarrollo de educación general
(GED por sus siglas en Ingles) _____

Grados 10 – 11 _____

Grados 7 – 9 _____

Grados 1 – 6 _____

Desconocidos _____

1.5b ¿Cuantos años de escuela ha completado? _____ años**1.6 ¿Cual es su (sus) ocupación (es) actual? Por favor escriba su respuesta (s) abajo:**

sitio del estudio _____ # de identificación _____

Cuestionario del cuidador -Referencia

2. SUS CREENCIAS ACERCA DE LOS DIENTES DE LOS NIÑOS Y EL CUIDADO DENTAL

Los padres tienen diferentes creencias acerca de los dientes de los niños/as y obtener el cuidado dental. *Por favor diganos cuanto está usted de acuerdo o desacuerdo con las siguientes declaraciones al circular el número que mejor se ajuste a su respuesta.*

	Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
2a. Eventualmente la mayoría de los niños/as desarrollan caries dentales	1	2	3	4	5
2b. Las caries en los dientes de leche no importan ya que de todos modos se caen	1	2	3	4	5
2c. No sé cómo llevar a mi niño/a al dentista para que le arreglen sus caries.	1	2	3	4	5
2d. Si me llevé a mi hijo al dentista, no haría ninguna diferencia si o no él/ella desarrolle caries.	1	2	3	4	5
2e. Yo intentaré llevar a mi niño/a al dentista al menos <u>una vez</u> al año.	1	2	3	4	5
2f. No puedo hacer que mi niño/a vaya al dentista.	1	2	3	4	5
2g. El dentista es la mejor persona para prevenir las caries de mi niño/a.	1	2	3	4	5
2h. No sé cómo cepillarle los dientes apropiadamente a mi niño/a.	1	2	3	4	5
2i. Si le ayudo a mi niño/a cepillarse todos los días, no hará ninguna diferencia si o no él/ella desarrolle caries	1	2	3	4	5
2j. Intento cepillarle los dientes a mi niño/a <u>dos veces</u> al día.	1	2	3	4	5
2k. No puedo hacer que mi niño/a cepille sus dientes <u>dos veces</u> al día.	1	2	3	4	5

sitio del estudio _____ # de identificación _____

Cuestionario del cuidador -Referencia

3. SUS PENSAMIENTOS ACERCA DE VISITAR AL DENTISTA

Las siguientes preguntas son acerca de cómo usted se siente en el dentista. Díganos cuan ansioso usted se sentiría en las siguientes situaciones *haciendo un círculo al número que mejor se adapte a su respuesta.*

Como se sentiría usted si...	Extremadamente ansioso	Muy ansioso	Bastante ansioso	Ligeramente ansioso	Nada ansioso
3a. Va a ir al dentista MANANA para TRATAMIENTO?	1	2	3	4	5
3b. ¿Está sentado en la SALA DE ESPERA (esperando por tratamiento)?	1	2	3	4	5
3c. ¿Está a punto de que le PERFOREN UN DIENTE?	1	2	3	4	5
3d. ¿Está a punto de tener sus dientes ESCALADOS y PULIDOS?	1	2	3	4	5
3e. ¿Está a punto de ponerle una INYECCIÓN de ANESTESIA LOCAL en sus encillas?	1	2	3	4	5

4. SUS PENSAMIENTOS ACERCA DE LLEVAR A SU NIÑO/A AL DENTISTA

4a. Las siguientes preguntas son acerca de llevar a su niño/a al dentista por cualquier razón. *Por favor circule el número que mejor se adapte a su respuesta.*

	Completamente en desacuerdo	Desacuerdo	Neutral	De acuerdo	Totalmente de acuerdo
4a1. Yo <u>quiero</u> llevar a mi niño al dentista	1	2	3	4	5
4a2. Yo <u>planeo</u> llevar a mi niño al dentista	1	2	3	4	5

sitio del estudio _____ # de identificación _____

Cuestionario del cuidador -Referencia

4b. Las siguientes preguntas son acerca de cómo usted se siente acerca de llevar a su niño/a al dentista para cuidado preventivo (chequeos, limpiezas, aplicación de fluoruro) y tratamientos dentales (arreglar caries) Y lo que otros piensan acerca de llevar a su niño/a al dentista para cuidado preventivo y de tratamiento dental. *Díganos como se siente, al hacer un círculo en el número que mejor se adapte a su respuesta.*

Mi sentimiento acerca del dentista es que se atraviesa en el camino si llevo a mi niño/a al dentista para ...	Completa- mente en desacuerdo	Desacuerdo	Neutral	De acuerdo	Totalmente de acuerdo
	1	2	3	4	5
4b1. Cuidado Preventivo					
4b2. Tratamiento Dental					

4c. – 4d.

Personas importantes para mí ...	Completa- mente en desacuerdo	Desacuerdo	Neutral	De acuerdo	Totalmente de acuerdo
	1	2	3	4	5
4c1. Piensan que debería llevar a mi niño/a al dentista dos veces al año					
4c2. Aprobarían si tuviera que llevar a mi niño/a al dentista dos veces al año					
4c3. Llevan a su niño dos veces al año					
4d1. Piensan que cuando se encuentre un problema en un diente debería llevar a mi niño/a al dentista					
4d2. Aprobarían que llevara a mi niño/a al dentista cuando se encuentre un problema en el diente					
4d3. Llevan a su niño/a al dentista cuando se encuentre un problema en un diente					

sitio del estudio _____ # de identificación _____

Cuestionario del cuidador -Referencia

4e. Algunas veces los padres atrasan el cuidado dental de su niño/a cuando otras cosas se presentan en el camino. ¿Qué probabilidades hay que lleve a su niño/a al dentista cuando lo siguiente le pase? Por favor circule el número que mejor se adopte a su respuesta.

Que probabilidades hay que usted lleve a su niño/a al dentista cuando usted está ...	Muy Probable	Moderadamente probablemente	Possiblemente	No hay probabilidad
4e1. Bajo mucho estrés	1	2	3	4
4e2. Deprimida	1	2	3	4
4e3. Ansiosa	1	2	3	4
4e4. Sintiéndose que no tiene el tiempo (muy ocupado)	1	2	3	4
4e5. Cansada	1	2	3	4
4e6. Preocupada por otras cosas en su vida	1	2	3	4
4e7. Molesta por su niño/a llorando	1	2	3	4
4e8. Molesta porque su niño/a no se está quieto para que el dentista lo examine	1	2	3	4
4e9. Su niño/a le dijo que no quiere ir al dentista	1	2	3	4

sitio del estudio _____ # de identificación _____

Cuestionario del cuidador -Referencia

5. Sus sentimientos y pensamientos durante el último mes

Para cada pregunta siguiente, *por favor circule cuan frecuente sintió o pensó de esa manera en el último mes.*

	Muy amenudo	Bastante amenudo	Algunas veces	Casi nunca	Nunca
5a. ¿En el último mes, con que frecuencia se ha sentido que no ha podido controlar las cosas importantes en su vida?	0	1	2	3	4
5b. ¿En el último mes, con que frecuencia se ha sentido confiado acerca de sus habilidades de manejar sus problemas personales?	0	1	2	3	4
5c. ¿En el último mes, que frecuencia se ha sentido que las cosas iban a su manera?	0	1	2	3	4
5d. ¿En el último mes, con que frecuencia se ha sentido que las dificultades se acumulan tan alto que no podía solucionarlas?	0	1	2	3	4

6. SUS HÁBITOS DE LECTURA

Las siguientes preguntas son acerca de sus materiales de lectura. Por favor haga un círculo en cuan a menudo usted hace lo siguiente

	Muy A menudo	Bastante A menudo	Algunas Veces	Casi Nunca	Nunca
6a. ¿Alguna vez lee libros por su propia cuenta?	0	1	2	3	4
6b. ¿Cuán a menudo tiene a alguien que le ayude a leer materiales relacionados con salud?	0	1	2	3	4
6c. ¿Qué confiado se siente al llenar usted solo formularios médicos/dentales?	0	1	2	3	4
6d. ¿Cuán a menudo usted tiene problemas aprendiendo acerca de su condición médica o dental porque tiene dificultad leyendo?	0	1	2	3	4

sitio del estudio _____ # de identificación _____

Cuestionario del cuidador -Referencia

7. COMPORTAMIENTO SOBRE SU SALUD DENTAL

Por favor haga un círculo en la respuesta que mejor se adapte a *usted*.

7.1 ¿Tiene un dentista al cual puede usted ir si necesita cuidado dental?

a) Si

b) No

7.2 ¿Hace cuento tiempo ha usted visitado a un dentista o clínica dental por alguna razón?

a) Seis meses o menos

b) Más de 6 meses pero no más de 1 año (entre 6 meses y 1 año)

c) En los 2 últimos años (entre 1 y 2 años)

d) En los últimos cinco años (entre 2 y 5 años)

e) Más de 5 años

f) Nunca

g) No se

7.3 ¿Cuan a menudo ve usted a un dentista o higienista dental?

a) al menos 1 vez al año

b) cada 2 años

c) menos de cada 2 años

d) cuando es necesario, no tengo un horario regular

e) otro, por favor especifique _____

f) nunca o ya no voy

g) no se

7.4 ¿Cual fue la razón principal de su última visita de cuidado dental?

a) fui por un chequeo, examen o limpieza

b) había algo mal, me molestaba o dolía

c) fui de nuevo por tratamiento que el dentista descubrió en un examen previo

d) otro, por favor especifique _____

e) no se

sitio del estudio _____ # de identificación _____

Cuestionario del cuidador -Referencia

7.5 POR FAVOR CONTESTE SOLO SI USTED NO HA SIDO VISTO POR UN DENTISTA EN LOS ULTIMOS 2 AÑOS (si usted contesto d, e o f a la pregunta 7.2)

Si usted no fue a una clínica dental en los *últimos 2 años*, es porque ...

(Por favor haga un círculo en la que aplique)

- a) no necesitaba ir, mi niño/a no tenía problemas dentales
- b) pensé que los problemas dentales de mi niño/a desaparecerían
- c) estaba muy ocupado o imposible de tomar tiempo libre del trabajo
- d) falta de transportación
- e) el cuidado dental preventivo es muy caro
- f) mi niño/a no tiene seguro dental o Medicaid (seguro con el estado)
- g) se me hizo imposible el hacer una cita para mi niño/a
- h) se me hizo imposible dejar a mi otro niño(a)/ niños(as) para ir a la cita
- i) otra razón, por favor especifique

7.6 ¿Durante el *último mes* estuvo usted cubierto por un plan del gobierno tal como Medicaid?

- a) Si
- b) No
- c) No se

7.7 ¿Durante el *último mes* estuvo usted cubierto por un plan de seguro dental obtenido en privado o por un empleador actual o la unión? Incluyendo membresía en una organización de mantenimiento de salud (HMO por sus siglas en Ingles)

- a) Si
- b) No
- c) No Se

7.8 ¿Cuan a menudo piensa usted que el costo del cuidado dental es razonable?

- a) nunca
- b) algunas veces
- c) usualmente
- d) siempre
- e) no se

sitio del estudio _____ # de identificación _____

Cuestionario del cuidador -Referencia

7.9 ¿Cuan a menudo se cepilla usted sus dientes?

- a) más de dos veces al día
- b) dos veces al día
- c) una vez al día
- d) una vez a la semana
- e) nunca

7.10 ¿Cuan a menudo se pasa usted el hilo dental?

- a) más de dos veces al día
- b) dos veces al día
- c) una vez al día
- d) una vez a la semana
- e) algunas veces a la semana
- f) nunca

7.11 ¿Ha tenido usted dolor de diente o caries en los últimos 12 meses?

- a) Si
- b) No

7.12 ¿ Ha tenido usted sangramiento de encillas o le han dicho que tiene una enfermedad en sus encillas en los *últimos 12 meses*?

- a) Si
- b) No

7.13 ¿Cómo describiría usted la salud de su boca y dientes?

- a) excelente
- b) muy buena
- c) buena
- d) regular
- e) mala

sitio del estudio _____ # de identificación _____

Cuestionario del cuidador -Referencia

7.14 ¿Ha perdido usted de ir al trabajo o escuela en los últimos 12 meses porque usted ha tenido problemas dentales?

- a) Si → Por favor responda la pregunta 7.14a
- b) No

7.14a ¿Cuantas horas de trabajo o escuela perdió? _____ horas

7.15 ¿Vio usted a un dentista regularmente (1-2 veces al año) cuando era niño/a entre las edades de 7 - 12?

- a) Si
- b) No
- c) No se

7.16 ¿Cuando era un niño/a entre las edades de 7 -12 lo veían sus padres cuando usted se cepillaba los dientes?

- a) Si
- b) No
- c) No se

7.17 ¿Cuando era un niño/a entre las edades de 7 -12 le hablaban sus padres acerca de la importancia del cuidado dental?

- a) Si
- b) No
- c) No se

sitio del estudio _____ # de identificación _____

Cuestionario del cuidador -Referencia

8. EL COMPORTAMIENTO DEL CUIDADO DENTAL DE SU NIÑO/APor favor haga un círculo en la letra que mejor se adapte a su respuesta acerca de su niño/a.**8.1 Durante una semana *ideal*, ¿cuán frecuente se cepilla los dientes su niño/a?**

- a) no se cepilla sus dientes
- b) menos de una vez a la semana
- c) una o dos veces a la semana
- d) un día si un día no
- e) casi todos los días
- f) una vez al día
- g) dos veces al día
- h) mas de 2 veces al día
- i) no se

8.2 ¿Ha sido alguna vez su niño/a visto por un dentista?

- a) Si → Por favor responda la pregunta 8.2a
- b) No
- c) No se

8.2a Que edad tenía su niño/a cuando fue su primera visita con el dentista?

8.3 ¿Durante los *últimos 12* meses, cuantas veces su niño/a vio a un doctor, enfermera u otro proveedor de salud para prevenir cuidado médico tal como un examen físico o chequeo de bienestar del niño? (Por favor no incluya visitas cuando su niño estaba enfermo o cuando algo le estaba molestando)

Número de veces _____

8.4 ¿Durante los *últimos 12* meses, cuantas veces su niño ha visto al dentista para prevenir cuidado dental tales como chequeos, limpiezas dentales, y fluoruro? (Por favor no incluya visitas cuando su niño/a estuvo con dolor o cuando algo le estaba molestando)

Número de veces _____

sitio del estudio _____ # de identificación _____

Cuestionario del cuidador -Referencia

8.4a Si contestó al menos una vez en la pregunta 8.4, fue este lugar un:

- a) oficina del dentista
- b) departamento de emergencia
- c) hospital
- d) clínica
- e) otro, por favor escriba aquí _____

8.5 ¿Durante los últimos 12 meses, recibió su niño/a todos los cuidados dentales de rutina que necesitaba (exámenes de chequeo, limpiezas dentales y fluoruro)?

- a) Si
- b) No → por favor conteste la pregunta 8.5a
- c) No se

8.5a ¿Por qué su niño/a NO recibió todo el cuidado preventivo que necesitaba?

- a) no necesitaba ir, mi niño/a no tenía problemas dentales
- b) pensé que los problemas dentales de mi niño/a desaparecerían
- c) estaba muy ocupado o imposible de tomar tiempo libre del trabajo
- d) falta de transportación
- e) el cuidado dental preventivo es muy caro
- f) mi niño/a no tiene seguro dental o Medicaid (seguro con el estado)
- g) se me hizo imposible el hacer una cita para mi niño/a
- h) se me hizo imposible dejar a mi otro niño(a)/ niños(as) para ir a la cita
- i) otra razón, por favor especifique _____

8.6 ¿Durante el último mes, tuvo su niño/a algún tipo de cobertura dental? Tal como plan privado, plan preferencial (como una membresía de organización de mantenimiento de salud (HMO por sus siglas en Ingles) o plan de gobierno (como Medicaid)

- a) Si → Por favor conteste la pregunta 8.6a
- b) No
- c) No se

8.6a ¿Estuvo su niño/a asegurado por Medicaid o el programa de seguro de salud de niños/as (S-CHIP por sus siglas en Ingles)?

- a) Si
- b) No
- c) No se

sitio del estudio _____ # de identificación _____

Cuestionario del cuidador -Referencia

8.7 ¿Hay un lugar al que su niño/a usualmente va cuando necesita tratamiento para sus problemas dentales, como caries o dolor de dientes?

- a) Si → por favor responda la pregunta 8.7a
- b) No
- c) No se

8.7a Si su respuesta es **SI**, Es este un lugar:

- a) oficina del dentista
- b) departamento de emergencia
- c) hospital
- d) clínica
- e) otro, por favor escriba aquí _____

8.8 Algunas veces personas tienen problemas en obtener todo el tratamiento dental que necesitan. Durante los *últimos 12 meses*, ¿hubo alguna vez que su niño/a necesito cuidado dental pero fue retrasado o no lo recibió?

- a) Si → Por favor responda las preguntas 8.8a y 8.8b

- b) No
- c) No se

Por Favor, Saltase al Número 8.9

8.8a Después que un problema fue encontrado por un proveedor dental, ¿qué tipo de tratamiento fue atrasado o no fue recibido? *Por favor haga un círculo en todas las que apliquen.*

- a) rellenos
- b) extracciones (sacarse un diente)
- c) corona (casquillo de metal)
- d) terapia de pulpa (endodoncia en diente de leche)
- e) enfermedad en las encillas
- f) otro, por favor especifique
- g) no me acuerdo

sitio del estudio _____ # de identificación _____

Cuestionario del cuidador -Referencia

8.8b ¿Porque su niño no obtuvo todo el cuidado dental que necesitaba? Aquí hay algunas razones comunes--- *por favor haga un círculo en las que apliquen.*

- a) Cuesta mucho
- b) Mi niño no tiene seguro dental o Medicaid
- c) Mi familia tiene problemas con nuestro plan de cuidado de salud
- d) No puedo encontrar un dentista que acepte el seguro de mi niño/a
- e) No hay dentistas disponibles en mi área / tengo problema de transporte
- f) Es difícil poder obtener horarios convenientes para las citas / mi niño/a no puede obtener una cita
- g) El dentista no sabe cómo tratar o proveer cuidado a mi niño/a
- h) Yo estaba insatisfecho con el dentista
- i) No sabía a dónde llevar a mi niño/a para tratamiento
- j) Mi niño/a rehúsa a ir
- k) El tratamiento de mi niño/a es continuo (se está llevando a cabo)
- l) Mi niño necesita una referencia y no podemos obtener una
- m) Otra, por favor especifique _____

8.9 ¿Durante los *últimos 12* meses, usted, un doctor o dentista pensaron que su niño/a necesitaba ver a un especialista dental (por ejemplo, un dentista pediatra)?

- a) Si →Por favor responda la pregunta 8.9a
- b) No
- c) No se

8.9a ¿Durante los *últimos 12* meses, cuantos problemas - si alguno- tuvo para obtener el cuidado del especialista que su niño/a necesitaba?

- a) un problema grande
- b) un problema pequeño
- c) no hubo ningún problema
- d) no se

8.10 Un dentista personal es un profesional de salud que conoce bien a su niño/a y está familiarizado con el historia de salud dental de su niño/a. Tiene uno o más personas que usted piensa como el dentista personal de su niño/a?

- a) Si, 1 persona
- b) Si, más de 1 persona
- c) No

¡Gracias!

Site: _____ ID# _____

Estudio de Acceso de la Familia al Dentista

**Sus Sentimientos
Acerca de la Caries**

29 de Enero de 2015

2-Semanas
IPQ-RD

Site: _____ ID# _____

Instrucciones:

Nosotros estamos interesados en su punto de vista acerca de las caries en su niño/a (caries en el diente). Por favor indique cuanto usted está de acuerdo o desacuerdo con las siguientes oraciones acerca de la caries al hacer un circulo en las siguientes respuestas de cada pregunta: **totalmente de acuerdo (1), de acuerdo (2), ni de acuerdo ni en desacuerdo (3), desacuerdo (4), en total desacuerdo (5)**.

Por favor digan si cree que cada una de las siguientes es un síntoma relacionado a caries dentales en los niños/as:

1. Dolor de diente
- 1b. Dientes sensibles a lo caliente o helado
- 1c. Hoyo en el diente
- 1d. Manchas blancas u oscuras en los dientes
- 1e. Inflamación en la cara o encillas (incluyendo una postemilla o absceso)

	Yes	No
1a. Dolor de diente		
1b. Dientes sensibles a lo caliente o helado		
1c. Hoyo en el diente		
1d. Manchas blancas u oscuras en los dientes		
1e. Inflamación en la cara o encillas (incluyendo una postemilla o absceso)		

Por favor haga un círculo en el número que de la mejor respuesta para cada pregunta. Si su niño/a no ha tenido caries, por favor responda como se sentiría si ellos tuviera.

Acerca de su niño/a:	Totalmente de acuerdo	De acuerdo	NI de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
2. Las caries en mi niño/a es una enfermedad seria.	1	2	3	4	5
3. Las caries en mi niño/a han tenido un gran efecto en <u>su vida</u> .	1	2	3	4	5
4. Las caries en mi niño/a han tenido un gran efecto en como <u>el/ella</u> sonríe.	1	2	3	4	5
5. Las caries en mi niño/a han tenido un gran efecto en como <u>el/ella</u> se comporta en la casa.	1	2	3	4	5
6. Las caries en mi niño/a han tenido un gran efecto en como hace <u>el/ella</u> su trabajo en la escuela.	1	2	3	4	5
7. Las caries en mi niño/a han tenido un gran efecto en como se siente acerca de <u>el/ella</u> misma.	1	2	3	4	5
8. Las caries en mi niño/a es una incapacidad.	1	2	3	4	5

Site: _____ ID# _____

Acerca de usted:	Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
9. Las caries en mi niño/a tienen un gran impacto en <u>mi vida</u> .	1	2	3	4	5
10. Simplemente no puedo vivir con las caries de <u>mi niño/a</u> .	1	2	3	4	5
11. Las caries en mi niño/a tienen un gran efecto en como otros <u>me</u> ven.	1	2	3	4	5
12. Las caries en mi niño/a <u>me</u> ha causado problemas de dinero.	1	2	3	4	5
13. Las caries en mi niño/a tienen un gran efecto en <u>mi autoestima</u> .	1	2	3	4	5

Acerca de su niño/a:	Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
14. Hay mucho que se puede hacer para mejorar las caries en <u>mi niño/a</u> .	1	2	3	4	5
15. El tratamiento en <u>mi niño/a</u> le ayudara a mejorar sus caries.	1	2	3	4	5
16. El mejoramiento en las caries de <u>mi niño/a</u> no va a cambiar por casualidad o destino.	1	2	3	4	5
17. Lo que haga <u>mi niño/a</u> decidirá si sus caries mejoran o empeoran.	1	2	3	4	5

Acerca de usted:	Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
18. Hay mucho que <u>yo puedo</u> hacer para controlar los síntomas de la caries de mi niño/a.	1	2	3	4	5
19. Lo que <u>yo haga</u> decide si las caries de mi niño/a se mejoran o empeoran.	1	2	3	4	5
20. Es mucho lo que <u>yo puedo</u> hacer para parar las caries de mi niño/a una vez que empiezan.	1	2	3	4	5
21. Es mucho lo que <u>yo puedo</u> hacer para prevenir las caries en mi niño/a.	1	2	3	4	5

Site: _____ ID# _____

Acerca de su niño/a:

	Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
--	-----------------------	------------	--------------------------------	------------	---------------------

22. Las caries de mi niño/a no se mejoraran con el tiempo.

23. Es probable que las caries de mi niño/a que sean duraderas y no a corto plazo.

1	2	3	4	5
---	---	---	---	---

1	2	3	4	5
---	---	---	---	---

Acerca de su niño/a:

	Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
--	-----------------------	------------	--------------------------------	------------	---------------------

24. Las caries en mi niño/a podrían cambiar de vez en cuando.

25. Habrá momentos cuando los síntomas de las caries de mi niño/a se empeoren y tiempos cuando se mejoren.

1	2	3	4	5
---	---	---	---	---

1	2	3	4	5
---	---	---	---	---

Acerca de usted:

	Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
--	-----------------------	------------	--------------------------------	------------	---------------------

26. Tengo un claro entendimiento de las caries de mi niño/a.

27. Los síntomas de las caries de mi niño/a no son confusos para mí.

1	2	3	4	5
---	---	---	---	---

1	2	3	4	5
---	---	---	---	---

Acerca de usted:

	Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
--	-----------------------	------------	--------------------------------	------------	---------------------

28. Me pongo muy triste y molesto cuando pienso que mi niño/a está sufriendo de caries.

29. Ver a mi niño/a con caries me preocupa.

30. Ver a mi niño/a con caries me hace sentir enojado.

31. Ver a mi niño/a con caries me hace sentir impotente.

1	2	3	4	5
---	---	---	---	---

1	2	3	4	5
---	---	---	---	---

1	2	3	4	5
---	---	---	---	---

1	2	3	4	5
---	---	---	---	---

Site: _____ ID# _____

32. Causas de las caries en los niños/as:

Nosotros estamos interesados en su punto de vista acerca de las caries de su niño/a. No hay una respuesta correcta. Nosotros estamos interesados en sus propias ideas acerca de las causas de las caries de su niño/a en lugar de lo que otros (incluyendo doctores o familia) puedan haberle dicho. Abajo esta una lista de posibles causas.

Por favor indique cuanto usted está de acuerdo o desacuerdo con cada causa haciendo un círculo al número que mejor se adapte a su respuesta: *totalmente de acuerdo (1), de acuerdo (2), ni de acuerdo ni de desacuerdo (3), desacuerdo (4), totalmente en desacuerdo (5)*.

Por favor haga un círculo en el número de la mejor respuesta

	Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
32a. La causa de la caries en mi niño/a es el estrés o preocupación.	1	2	3	4	5
32b. La caries corre en mi familia.	1	2	3	4	5
32c. Un germen o virus causó la caries de mi niño/a.	1	2	3	4	5
32d. La dieta o hábitos alimenticios causaron la caries en mi niño/a.	1	2	3	4	5
32e. Casualidad o suerte causaron las caries de mi niño/a.	1	2	3	4	5
32f. El pobre cuidado dental causó la caries de mi niño/a.	1	2	3	4	5
32g. Algo que yo hice como padre/madre causó la caries a mi niño/a.	1	2	3	4	5
32h. Mis pensamientos negativos causaron la caries de mi niño/a.	1	2	3	4	5
32i. Los problemas de familia o preocupaciones causaron la caries en mi niño/a.	1	2	3	4	5
32j. Mis sentimientos (sentirme decaído, ansioso) le causó la caries a mi niño/a.	1	2	3	4	5
32k. La falta de habilidad de pelear la infección causó la caries de mi niño/a.	1	2	3	4	5

Site: _____ ID# _____

33. Por favor escriba en orden las 3 cosas más importantes que usted cree ahora causaron la caries de su niño/a. Usted puede usar cualquiera de los artículos de las preguntas anteriores o que tenga otras ideas propias.

Las causas más importantes para mí son:

1st _____

2nd _____

3rd _____

Sitio del estudio _____ # de identificación _____

2-Semanas Seguimiento

Estudio de Acceso de la Familia al Dentista

Cuestionario del Cuidador

29 de Junio, 2015

2-Semanas Seguimiento

Page 1

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Sitio del estudio _____ # de identificación _____

2-Semanas Seguimiento

1. LLEVANDO A SU NIÑO/A AL DENTISTA

1.1 ¿Después de la evaluación visual en la escuela, visito su niño/a al dentista?

- a) Si → Por favor VAYA A la Pregunta 1.2
- b) No, pero hice una cita con el dentista → Por favor SÁLTASE a la Pregunta 1.5
- c) No, y no he hecho la cita con el dentista → Por favor SÁLTASE a la Pregunta 1.6

Si contestó SI a la Pregunta 1.1 de arriba, por favor responda a las siguientes preguntas:

1.2 ¿Cuál es el nombre de la clínica dental/dentista donde usted llevó a su niño/a?

1.3 ¿Llevó la carta de referencia (de la evaluación visual dental de la escuela) con usted al dentista?

- a) Si
- b) No

1.4 ¿Completo su niño/a el tratamiento dental que necesitaba?

- a) Si

Si es SI, ¿cuántas visitas fueron necesarias para completar el tratamiento dental de su niño/a? _____

- b) No, pero tiene una cita de seguimiento

Si NO, ¿Cuando está programada la cita de seguimiento? _____

- c) No

Si NO, ¿Por qué su niño/a no completo el tratamiento dental? _____

- d) Don't know

Por favor VAYA a la Pregunta 1.5

2

Sitio del estudio _____ # de identificación _____

2-Semanas Seguimiento

Si usted contestó SI o NO, pero he hecho una cita a la Pregunta 1.1 de arriba, por favor responda a la siguiente pregunta:

1.5 ¿Había alguna articulo abajo que le ayudo a decidir a llevar a su niño/a al dentista ó hacer una cita con el dentista?

Por favor circule todos los que apliquen.

- a) La carta de referencia
- b) Información de mitos y hechos de la salud dental de los niños/as
- c) Consejos útiles para el cuidado dental de su niño/a
- d) Información en hacer citas dentales para su niño/a
- e) Conocer acerca de los dentistas en su área
- f) El alcance individual en la escuela del niño/a
- g) No se

¡Gracias!

Sitio del estudio _____ # de identificación _____

2-Semana Seguimiento

Si contestó NO, y no he hecho una cita a la Pregunta 1.1 de arriba, por favor responda a las siguientes preguntas:

1.6 Las siguientes preguntas son acerca de llevar a su niño/a al dentista.

Por favor circule el número que mejor se adapte a su respuesta

	Completeme nte en desacuerdo	Desacuerdo	Neutral	De acuerdo	Totalmente de acuerdo
1.6a Yo <u>quiero</u> llevar a mi niño al dentista	1	2	3	4	5
1.6b Yo <u>planeo</u> llevar a mi niño al dentista	1	2	3	4	5

1.7 ¿Porque su niño NO ha podido visitar al dentista desde la evaluación dental en la escuela? Aquí hay algunas razones comunes de otros padres por favor circule todas las que apliquen.

- a) Cuesta mucho
- b) Mi niño no tiene seguro dental o Medicaid
- c) Mi familia tiene problemas con nuestro plan de cuidado de salud
- d) No puedo encontrar un dentista que acepte el seguro de mi niño/a
- e) No hay dentistas disponibles en mi área / tengo problema de transporte
- f) Es difícil poder obtener horarios convenientes para las citas / mi niño/a no puede obtener una cita
- g) El dentista no sabe cómo tratar o proveer cuidado a mi niño/a
- h) Yo estaba insatisfecho con el dentista
- i) No sabía a dónde llevar a mi niño/a para tratamiento
- j) Mi niño/a rehúsa a ir
- k) El tratamiento de mi niño/a es continuo (se está llevando a cabo)
- l) Otra, por favor especifique _____

¡Gracias!

Page 4

Site: _____ ID#_____

Estudio de Acceso de la Familia al Dentista

**Sus Sentimientos
Acerca de la Caries**

29 de Enero de 2015

**Seguimiento
IPQ-RD**

Site: _____ ID# _____

Instrucciones:

Nosotros estamos interesados en su punto de vista acerca de la caries en su niño/a (caries en el diente). Por favor indique cuanto usted está de acuerdo o desacuerdo con las siguientes oraciones acerca de la caries al hacer un círculo en las siguientes respuestas de cada pregunta: *totalmente de acuerdo (1), de acuerdo (2), ni de acuerdo ni en desacuerdo (3), desacuerdo (4), en total desacuerdo (5)*.

1. *Por favor díganos si cree que cada una de las siguientes es un síntoma relacionado a caries dentales en los niños/as:*

1a.	Dolor de diente	Yes	No
1b.	Dientes sensibles a lo caliente o helado	Yes	No
1c.	Hoyo en el diente	Yes	No
1d.	Manchas blancas u oscuras en los dientes	Yes	No
1e.	Inflamación en la cara o encillas (incluyendo una postemilla o absceso)	Yes	No

Por favor haga un círculo en el número que de la mejor respuesta para cada pregunta. Si su niño/a no ha tenido caries, por favor responda como se sentiría si ellos tuviera.

Acerca de su niño/a:	Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
2. Las caries en mi niño/a es una enfermedad seria.	1	2	3	4	5
3. Las caries en mi niño/a han tenido un gran efecto en su vida.	1	2	3	4	5
4. Las caries en mi niño/a han tenido un gran efecto en como <u>el/ella</u> sonrie.	1	2	3	4	5
5. Las caries en mi niño/a han tenido un gran efecto en como <u>el/ella</u> se comporta en la casa.	1	2	3	4	5
6. Las caries en mi niño/a han tenido un gran efecto en como hace <u>el/ella</u> su trabajo en la escuela.	1	2	3	4	5
7. Las caries en mi niño/a han tenido un gran efecto en como se siente acerca de <u>el/ella</u> misma.	1	2	3	4	5
8. Las caries en mi niño/a es una incapacidad.	1	2	3	4	5

Site: _____ ID# _____

Acerca de usted:	Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
9. Las caries en mi niño/a tienen un gran impacto en <u>mi</u> vida.	1	2	3	4	5
10. Simplemente no puedo vivir con las caries de <u>mi</u> niño/a.	1	2	3	4	5
11. Las caries en mi niño/a tienen un gran efecto en como otros <u>me</u> ven.	1	2	3	4	5
12. Las caries en mi niño/a <u>me</u> ha causado problemas de dinero.	1	2	3	4	5
13. Las caries en mi niño/a tienen un gran efecto en <u>mi</u> autoestima.	1	2	3	4	5

Acerca de su niño/a:	Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
14. Hay mucho que se puede hacer para mejorar las caries en <u>mi</u> niño/a.	1	2	3	4	5
15. El tratamiento en <u>mi</u> niño/a le ayudara a mejorar sus caries.	1	2	3	4	5
16. El mejoramiento en las caries de <u>su</u> niño/a no va a cambiar por casualidad o destino.	1	2	3	4	5
17. Lo que haga <u>mi</u> niño/a decidirá si sus caries mejoran o empeoran.	1	2	3	4	5

Acerca de usted:	Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
18. Hay mucho que <u>yo</u> <u>puedo</u> hacer para controlar los síntomas de la caries de mi niño/a.	1	2	3	4	5
19. Lo que <u>yo</u> <u>haga</u> decide si las caries mi niño/a se mejora o empeoren.	1	2	3	4	5
20. Es mucho lo que <u>yo</u> <u>puedo</u> hacer para parar las caries de mi niño/a una vez que empiezan.	1	2	3	4	5
21. Es mucho lo que <u>yo</u> <u>puedo</u> hacer para prevenir las caries en mi niño/a.	1	2	3	4	5

Site: _____ ID# _____

Acerca de su niño/a:

Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
-----------------------	------------	--------------------------------	------------	---------------------

22. Las caries de mi niño/a no se mejorarán con el tiempo.

23. Es probable que las caries en mi niño/a sean duraderas y no a corto plazo.

1	2	3	4	5
---	---	---	---	---

1	2	3	4	5
---	---	---	---	---

Acerca de su niño/a:

Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
-----------------------	------------	--------------------------------	------------	---------------------

24. Las caries en mi niño/a podrían cambiar de vez en cuando.

25. Habrá momentos cuando los síntomas de las caries de mi niño/a se empeoran y tiempos cuando se mejoran.

1	2	3	4	5
---	---	---	---	---

1	2	3	4	5
---	---	---	---	---

Acerca de usted:

Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
-----------------------	------------	--------------------------------	------------	---------------------

26. Tengo un claro entendimiento de las caries de mi niño/a.

27. Los síntomas de las caries de mi niño/a no son confuso para mí.

1	2	3	4	5
---	---	---	---	---

1	2	3	4	5
---	---	---	---	---

Acerca de usted:

Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
-----------------------	------------	--------------------------------	------------	---------------------

28. Me pongo muy triste y molesto cuando pienso que mi niño/a está sufriendo de caries.

29. Ver a mi niño/a con caries me preocupa.

30. Ver a mi niño/a con caries me hace sentir enojado.

31. Ver a mi niño/a con caries me hace sentir impotente.

1	2	3	4	5
---	---	---	---	---

1	2	3	4	5
---	---	---	---	---

1	2	3	4	5
---	---	---	---	---

1	2	3	4	5
---	---	---	---	---

Site: _____ ID# _____

32. Causas de las caries en los niños/as:

Nosotros estamos interesados en su punto de vista acerca de las caries de su niño/a. No hay una respuesta correcta. Nosotros estamos interesados en sus propias ideas acerca de las causas de las caries de su niño/a en lugar de lo que otros (incluyendo doctores o familia) puedan haberle dicho. Abajo esta una lista de posibles causas.

Por favor indique cuanto usted está de acuerdo o desacuerdo con cada causa haciendo un círculo al número que mejor se adapte a su respuesta: *totalmente de acuerdo (1), de acuerdo (2), ni de acuerdo ni de desacuerdo (3), desacuerdo (4), totalmente en desacuerdo (5)*.

Por favor haga un círculo en el número de la mejor respuesta

	Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
32a. La causa de la caries en mi niño/a es el estrés o preocupación.	1	2	3	4	5
32b. La caries corre en mi familia.	1	2	3	4	5
32c. Un germen o virus causó la caries de mi niño/a.	1	2	3	4	5
32d. La dieta o hábitos alimenticios causaron la caries en mi niño/a.	1	2	3	4	5
32e. Casualidad o suerte causaron las caries de mi niño/a.	1	2	3	4	5
32f. El pobre cuidado dental causó la caries de mi niño/a.	1	2	3	4	5
32g. Algo que yo hice como padre/madre causó la caries a mi niño/a.	1	2	3	4	5
32h. Mis pensamientos negativos causaron la caries de mi niño/a.	1	2	3	4	5
32i. Los problemas de familia o preocupaciones causaron la caries en mi niño/a.	1	2	3	4	5
32j. Mis sentimientos (sentime decaído, ansioso) le causó la caries a mi niño/a.	1	2	3	4	5
32k. La falta de habilidad de pelear la infección causó la caries de mi niño/a.	1	2	3	4	5

Site: _____ ID# _____

33. Por favor escriba en orden las 3 cosas más importantes que usted cree ahora causaron la caries de su niño/a. Usted puede usar cualquiera de los artículos de las preguntas anteriores o que tenga otras ideas propias.

Las causas más importantes para mí son:

1st _____

2nd _____

3rd _____

Sitio del estudio: _____ # de identificación: _____

Cuestionario del cuidador Ultimo seguimiento

Estudio de Acceso de la Familia al Dentista

**Cuestionario del
Cuidador**

29 de Junio, 2015

Ultimo Seguimiento

Sitio del estudio: _____ # de identificación: _____

Cuestionario del cuidador Ultimo seguimiento

Fecha de la entrevista: _____
Mes día año

Iniciales del entrevistador: _____

1. INFORMACIÓN DE ANTECEDENTES**1.1 Su estado marital.** Por favor marque solo uno con una X.

Casado _____

Divorciado _____

Soltero _____

Separado _____

Derecho común _____

Viudo _____

Desconocido _____

1.2 ¿Si usted es el padre o la madre, ¿está el otro parente o madre viviendo con usted?

Si _____

No _____

1.3 Su educación.**1.3a ¿Cuantos años de escuela ha completado?** _____ años**1.3b. Su más alto nivel de educación completo.** Por favor, Marque solo uno con una X.

Título de posgrado _____

Algunos años de educación superior _____

Título de Universidad/Colegio _____

Algunos estudios de Universidad _____

Diploma de bachillerato /
examen de desarrollo de educación
general (GED por sus siglas en Inglés) _____

Grados 10 – 11 _____

Grados 7 – 9 _____

Grados 1 – 6 _____

Desconocidos _____

1.4 ¿Cual es su (sus) ocupación (es) actual? Por favor escriba su respuesta (s) abajo._____

Sitio del estudio: _____ # de identificación: _____

Cuestionario del cuidador Último seguimiento

2. SUS CREINCIAS ACERCA DE DIENTES DE LOS NIÑOS Y CUIDADO DENTAL

Los padres tienen diferentes creencias acerca de obtener cuidado dental de sus niños/as. Por favor diganos cuanto está usted de acuerdo o desacuerdo con las siguientes declaraciones al circular el número que mejor se ajuste a su respuesta.

	Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	Desacuerdo	En total desacuerdo
2a. Eventualmente la mayoría de los niños/as desarrollan caries dentales	1	2	3	4	5
2b. Las caries en los dientes de leche no importan ya que de todos modos se caen	1	2	3	4	5
2c. No sé cómo llevar a mi niño/a al dentista para que le arreglen sus caries.	1	2	3	4	5
2d. Si me llevé a mi hijo al dentista, no haría ninguna diferencia si o no él/ella desarrolle caries.	1	2	3	4	5
2e. Yo intentaré llevar a mi niño/a al dentista al menos <u>una vez</u> al año.	1	2	3	4	5
2f. No puedo hacer que mi niño/a vaya al dentista.	1	2	3	4	5
2g. El dentista es la mejor persona para prevenir las caries de mi niño/a.	1	2	3	4	5
2h. No sé cómo cepillarle los dientes apropiadamente a mi niño/a.	1	2	3	4	5
2i. Si le ayudo a mi niño/a cepillarse todos los días, no hará ninguna diferencia si o no él/ella desarrolle caries	1	2	3	4	5
2j. Intento cepillarle los dientes a mi niño/a <u>dos veces</u> al día.	1	2	3	4	5
2k. No puedo hacer que mi niño/a cepille sus dientes <u>dos veces</u> al día.	1	2	3	4	5

Sitio del estudio: _____ # de identificación: _____

Cuestionario del cuidador Último seguimiento

3. SUS PENSAMIENTOS ACERCA DE LLEVAR A SU NIÑO/A AL DENTISTA

3a – 3b. Las siguientes preguntas son acerca de lo que otros piensan acerca de llevar a su niño/a al dentista para cuidado preventivo y tratamiento dental. *Por favor diganos como se siente haciendo un círculo en el número que se ajuste a su respuesta.*

Personas importantes para mí ...	Completamente en desacuerdo	Desacuerdo	Neutral	De acuerdo	Totalmente de acuerdo
3a1. Piensan que debería llevar a <u>mi niño/a al menos una vez</u> al año.	1	2	3	4	5
3a2. Aprobarían si tuviera que llevar a <u>mi niño/a al dentista al menos una vez</u> al año.	1	2	3	4	5
3a3. Llevan a <u>su</u> niño/a al dentista <u>al menos una vez</u> al año.	1	2	3	4	5
<hr/>					
3b1. Piensan que cuando se encuentre un problema en un diente debería llevar a mi niño/a al dentista	1	2	3	4	5
3b2. Aprobarían que llevara a mi niño/a al dentista cuando se encuentre un problema en el diente	1	2	3	4	5
3b3. Llevan a su niño/a al dentista cuando se encuentre un problema en un diente	1	2	3	4	5

Sitio del estudio: _____ # de identificación: _____

Cuestionario del cuidador Ultimo seguimiento

3c. Algunas veces los padres atrasan el cuidado dental de su niño/a cuando otras cosas se presentan en el camino. ¿Qué probabilidades hay que lleve a su niño/a al dentista cuando lo siguiente pase? Por favor circule el número que mejor se adapte a su respuesta.

Que probabilidades hay que usted lleve a su niño/a al dentista cuando usted está ...	Muy Probable	Moderadamente probablemente	Possiblemente	No hay probabilidad
3c1. Bajo mucho estrés	1	2	3	4
3c2. Deprimida	1	2	3	4
3c3. Ansiosa	1	2	3	4
3c4. Sintiéndose que no tiene el tiempo (muy ocupado)	1	2	3	4
3c5. Cansada	1	2	3	4
3c6. Preocupada por otras cosas en su vida	1	2	3	4
3c7. Molesta por su niño/a llorando	1	2	3	4
3c8. Molesta porque su niño/a no se está quieto para que el dentista lo examine	1	2	3	4
3c9. Su niño/a le dijo que no quiere ir al dentista	1	2	3	4

Sitio del estudio: _____ # de identificación: _____

Cuestionario del cuidador Último seguimiento

4. EL COMPORTAMIENTO DEL CUIDADO DENTAL DE SU NIÑO/A*Por favor haga un círculo en la letra que mejor se adapte a su respuesta acerca de su niño/a.***4.1 Durante una semana *ideal*, ¿cuán frecuente se cepilla los dientes su niño/a?**

- a) No se cepilla sus dientes
- b) Menos de una vez a la semana
- c) Una o dos veces a la semana
- d) Un día si un día no
- e) Casi todos los días
- f) Una vez al día
- g) Dos veces al día
- h) Mas de 2 veces al día
- i) No se

4.2 ¿Desde el inicio del año escolar, tuvo su niño/a algún tipo de cobertura dental? Tal como plan privado, plan preferencial (como una membresía de organización de mantenimiento de salud (HMO por sus siglas en Ingles) o plan de gobierno (como Medicaid).

- a) Si → Por favor responda la pregunta 4.2a
- b) No
- c) No se

4.2a ¿Estuvo su niño/a asegurado por Medicaid o el programa de seguro de salud de niños/as (S-CHIP por sus siglas en Ingles)?

- a) Si
- b) No
- c) No se

4.3 ¿Hay un lugar al que su niño/a usualmente va cuando necesita tratamiento para su problemas dental, como caries o dolor de dientes?

- a) Si → Por favor responda la pregunta 4.3a
- b) No
- c) No se

Sitio del estudio: _____ # de identificación: _____

Cuestionario del cuidador Último seguimiento

4.3a Si su respuesta es SI, es este un lugar:

- a) Oficina del dentista
- b) Departamento de emergencia
- c) Hospital
- d) Clínica
- e) Otro, por favor escriba aquí _____

4.4 Algunas veces personas tienen problemas en obtener todo el tratamiento dental que necesitan. Desde el inicio del año escolar, ¿hubo alguna vez que su niño/a necesito cuidado dental pero fue retrasado o no lo recibió?

a) Si → Por favor responda la pregunta 4.4a

b) No



c) No se

Por favor sáltense la pregunta 4.5

4.4a Despues que un problema fue encontrado por un proveedor dental, ¿qué tipo de tratamiento fue atrasado o no fue recibido? Por favor haga un círculo en todas las que apliquen.

- a) Rellenos
- b) Extracciones (sacarse un diente)
- c) Corona (casquillo de metal)
- d) Terapia de pulpa (endodoncia en diente de leche)
- e) Enfermedad en las encillas
- f) Otro, por favor especifique
- g) No me acuerdo

4.5 ¿Visitó su niño/a al dentista después de la evaluación dental en la escuela?

a) Si → Vaya a la pregunta 5A

b) No → Vaya a la pregunta 5B

5A. SUS PENSAMIENTOS ACERCA DEL ESTUDIO

Si usted contestó SI a la Pregunta 4.5 (su niño visitó al dentista), por favor responda a las siguientes preguntas:

5.1 ¿Cuál es el nombre de la clínica dental/dentista donde usted llevó a su niño/a?

5.2 ¿Qué mes después de la evaluación dental llevo a su niño/a al dentista?

5.3 ¿Llevó la carta de referencia (de la evaluación visual dental de la escuela) con usted al dentista?

- a) Si
- b) No

5.4 ¿Completo su niño/a el tratamiento dental necesario?

- a) Si

Si es SI, ¿cuántas visitas fueron necesarias para completar el tratamiento dental de su niño/a?

- b) No, pero mi niño/a tiene una cita de seguimiento

Si NO, ¿cuándo es la cita de seguimiento? _____

- c) No

Si NO, ¿porque su niño/a no completo el tratamiento dental? _____

- d) No se

Por favor VAYA a la Pregunta 5.5

Sitio del estudio: _____ # de identificación: _____

Cuestionario del cuidador Último seguimiento

5.5 ¿Hubieron algunos puntos anteriormente que le ayudaron a usted a llevar a su niño al dentista?*Por favor circule todos los que apliquen.*

- a) La carta de referencia
- b) Información acerca de mitos y hechos acerca de la salud dental de los niños/as
- c) Consejos útiles para obtener cuidado dental para su niño/a
- d) Información en cómo hacer una cita dental para su niño/a
- e) Conocer acerca de los dentistas en su área
- f) El alcance individual
- g) No se

5.6 ¿Encontró que la carta de referencia fue fácil de entender?

- a) Si
- b) No

5.7 ¿En cuál grupo de estudio piensa usted que estuvo usted y su niño?

- a) En la carta estándar
- b) En la carta de mejoramiento
- c) En la carta de mejoramiento con materiales
- d) No se

¡GRACIAS!

Sitio del estudio: _____ # de identificación: _____

Cuestionario del cuidador Ultimo seguimiento

5.B SUS PENSAMIENTOS ACERCA DEL ESTUDIO

*Si usted contestó **NO** a la Pregunta 4.5 (su niño/a no visitó al dentista), por favor responda a las siguientes preguntas:*

5.1 Las siguientes preguntas son acerca de llevar a su niño/a al dentista. Por favor circule el número que es más apropiado para su respuesta

	Completamente en desacuerdo	Desacuerdo	Neutral	De acuerdo	Totalmente de acuerdo
5.1a Yo <u>quiero</u> llevar a mi niño/a al dentista	1	2	3	4	5
5.1b Yo <u>planeo</u> llevar a mi niño/a al dentista	1	2	3	4	5

5.2 Porque su niño/a NO ha podido ir a visitar al dentista desde la evaluación visual en la escuela? Aquí hay algunas razones de otros padres – por favor circule todas las que aplican.

- a) Cuesta mucho
- b) Mi niño no tiene seguro dental o Medicaid
- c) Mi familia tiene problemas con nuestro plan de cuidado de salud
- d) No puedo encontrar un dentista que acepte el seguro de mi niño/a
- e) No hay dentistas disponibles en mi área / tengo problema de transporte
- f) Es difícil poder obtener horarios convenientes para las citas / mi niño/a no puede obtener una cita
- g) El dentista no sabe cómo tratar o proveer cuidado a mi niño/a
- h) Yo estaba insatisfecho con el dentista
- i) No sabía a dónde llevar a mi niño/a para tratamiento
- j) Mi niño/a rehúsa a ir
- k) El tratamiento de mi niño/a es continuo (se está llevando a cabo)
- l) Otra, por favor especifique _____

Sitio del estudio: _____ # de identificación: _____

Cuestionario del cuidador Último seguimiento

5.3 ¿Hubieron algunos puntos anteriormente que le habría ayudado a usted a llevar a su niño al dentista? *Por favor circule todos los que apliquen.*

- a) La carta de referencia
- b) Información acerca de mitos y hechos acerca de la salud dental de los niños/as
- b) Consejos útiles para obtener cuidado dental para su niño/a
- c) Información en cómo hacer una cita dental para su niño/a
- d) Conocer acerca de los dentistas en su área
- e) El alcance individual
- f) No se

5.4 ¿Encontró que la carta de referencia fue fácil de entender?

- a) Si
- b) No

5.5 ¿En cuál grupo de estudio piensa usted que estuvo usted y su niño?

- a) En la carta estándar
- b) En la carta de mejoramiento
- c) En la carta de mejoramiento con materiales
- d) No se

¡GRACIAS!

