COordinated Oral health Promotion (CO-OP) Chicago Randomized Controlled Trial

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Principal Investigator: Molly A Martin

NIDCR Program Official: Dena Fischer

NIDCR Medical Monitor: Kevin McBryde

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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 or Clinical Site Investigator:

Signed: _____ Date: _____

Name: Molly A Martin, MD, MAPP

Title: Associate Professor

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LIST OF ABBREVIATIONS

AA	African American
ADL	Activities of Daily Living
AE	Adverse Event
CC	Coordinating Center
CDPH	Chicago Department of Public Health
CEDA	Community and Economic Development Association of Cook County, Inc
CHAOS	Confusion, Hubbub, and Order Scale
CHECK	Coordinated Healthcare for Complex Kids
CHWs	Community Health Workers
CI	Confidence Interval
CMP	Clinical Monitoring Plan
CRF	Case Report Form
CROMS	Clinical Research Operations Management Support
DSMB	Data and Safety Monitoring Board
FFR	Federal Financial Report
GCP	Good Clinical Practice Guidelines
HIPAA	Health Insurance Portability and Accountability Act
ICC	Intra-class correlation
ICER	Incremental cost-effectiveness ratio
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
ISM	Independent Safety Monitor
IRB	Institutional Review Board
ITT	Intention-to-treat
MAR	Missing at Random
MRC	Methodology Research Core
N	Number (typically refers to participants)
NIDCR	National Institute of Dental and Craniofacial Research, NIH, DHHS
NIH	National Institutes of Health
OCTOM	Office of Clinical Trials Operations and Management
OHI-MIS	Simplified Oral Hygiene Index – Maxillary Incisor

OHRP	Office for Human Research Protections
PHI	Personal Health Information
PI	Principal Investigator
PROMIS	Patient-Reported Outcomes Measurement Information System
RA	Research Assistant
SAE	Serious Adverse Event
TOST	Two One Sided Tests
UCSF	University of California at San Francisco
UIC	University of Illinois at Chicago
US	United States
WIC	Supplemental Nutrition Program for Women, Infants, and Children

PROTOCOL SUMMARY

Title: COordinated Oral health Promotion (CO-OP) Chicago Randomized Controlled Trial

Précis: COordinated Oral health Promotion (CO-OP) Chicago will bring together a team of clinical pediatricians and dentists, researchers, health psychologists, and policy experts to rigorously test the ability of an oral health promotion intervention to improve tooth brushing behaviors for children under the age of 3 years old. The primary intervention will be family-focused oral health education and support from community health workers (CHWs) delivered to families over one year. Participating study families will be recruited from pediatric primary care medical clinics and community social service centers (Women Infant and Children [WIC] Centers). Sites will be cluster randomized to intervention (CHW services) or usual care. Data on self-reported brushing frequency, plaque score, and other oral health behaviors will be collected at baseline, 6-months, and 12-months. The primary analysis will assess for differences in brushing frequency and plaque score between the two arms at 12-months.

Objectives: The primary study objective is to evaluate the efficacy of a one-year oral health CHW intervention, compared to usual care, to improve self-reported brushing frequency and observed plaque score in low income urban children under the age of 3 years old. This is achieved by offering CHW intervention to half of participating families and comparing them to families receiving usual care.

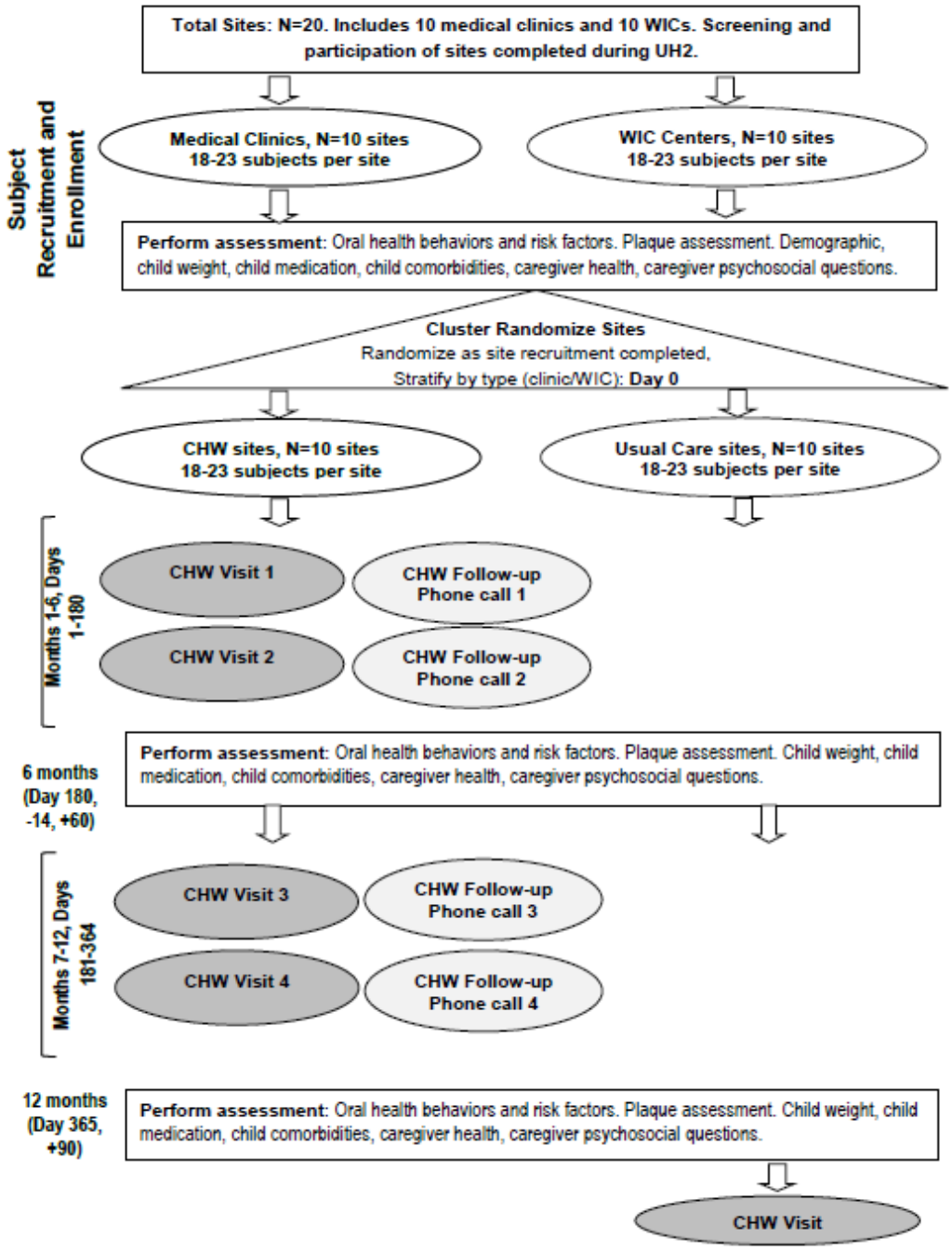
> Outcomes: frequency of brushing child's teeth, amount of plaque on child's teeth (plaque score)

The first exploratory objective is to determine if child tooth brushing behaviors are different in families whose oral health CHW is clinic-based compared to community-based. This is achieved by recruiting families from both primary care medical clinics and WIC centers. Sites are randomized to oral health CHW intervention (on the site level) or usual care to allow for an equal distribution of families receiving intervention and usual care in clinics and WIC centers.

> Outcomes: frequency of brushing child's teeth, amount of plaque on child's teeth (plaque score)

	The second exploratory objective is to determine the cost effectiveness of the CHW intervention compared to usual care. Outcomes: System-level (program) costs
Population:	Participants are caregiver/child dyads in Cook County, IL. We anticipate enrolling 420 caregiver/child dyads (18-23 from each site). To qualify, children must be aged 6-36 months with a minimum of two central maxillary incisors at least 50% erupted. Caregivers will be mostly female. Children will be equally male/female. Families will be almost entirely of African-American race and Hispanic ethnicity.
Phase:	II
Number of Sites:	20 sites: 10 primary care medical clinics and 10 WIC centers.
Description of Intervention:	CHWs trained in oral health will be assigned to half of the sites. Participants in these sites will be offered four in-person visits and follow-up phone calls over 12-months. These visits can occur at the location of the family's preference (recruitment site, home, or mutually-agreed upon other location). A core curriculum of oral health topics will be covered during visits, with an emphasis on developing and sustaining healthy oral health management routines for the entire family.
Study Duration:	34 months
Subject Participation Duration:	12 + 3 months.
Estimated Time to Complete Enrollment:	12 months

Schematic of Study Design:



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2 INTRODUCTION: BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

2.1 Background Information

Almost half of children 11 years old and younger suffer from dental caries, making caries one of the most common chronic diseases of childhood.[1] Low income and minority children bear a disproportionate portion of this burden and its associated morbidity.[2-5] Caries prevalence in Illinois and Chicago exceeds national figures, and Chicago area children have a high prevalence of untreated caries.[6] Factors that contribute to caries in children include insufficient fluoride exposure, unhealthy diets, and poor oral hygiene.[7-8]

Community health workers (CHWs) are frontline public health workers who serve as liaisons between health and social services and community residents to facilitate access to services and improve the quality and cultural competence of service delivery.[9] CHWs typically provide health education, information, assistance with services, and build individual and community capacity for health.[10] CHWs have been a part of health promotion and disease prevention efforts in US communities for several decades. CHW programs aim to address the health needs of under-served populations by training community members to be health educators who can reach their friends and neighbors effectively.[11-13] The basic rationale for this approach with underserved and hard-to-reach populations is that CHWs live in the same communities and have struggled with many of the same issues as their neighbors and thus share with the target population a similar base of knowledge and experiences.[12-13] CHWs utilize a model that empowers community members to identify their own needs and implement their own solutions with support from medical providers, which leads to improved community and personal self-efficacy.[14-16] There has been tremendous national interest in CHW interventions. This interest in part comes from an increasing number of studies supporting a role for CHW interventions in the improvement of health outcomes.[17-20] However there are limited data to support CHW intervention efficacy upon child oral health outcomes or associated family behaviors.[21-25]

COordinated Oral health Promotion (CO-OP) Chicago will test the efficacy of a family-focused CHW oral health intervention to improve tooth brushing behaviors for young children. CHWs will be based out of two settings: a clinical setting and a community setting. The results of this study will inform the need for and design of future research and programs that include oral health specific CHWs.

2.2 Rationale

The primary hypothesis this study tests is as follows: Participants receiving the oral health CHW intervention will have improved oral health behaviors, as measured using self-reported brushing frequency and observed plaque score, at 12-months compared to participants receiving usual care.

Caregiver directed oral health education has been shown to have a positive effect on knowledge, intended behavioral change (including snacking and sugar intake), and

caries prevalence.[21, 26-27] CHWs deliver education, social support and navigation services, which are important for low income families, but it remains unclear if oral health CHWs can influence knowledge and behaviors.[13,28]

The primary goal of CO-OP Chicago is to use a rigorous study design to determine the ability of a CHW-delivered oral health intervention to improve oral health behaviors, specifically tooth brushing, in high risk low income families. If the outcomes of this study indicate a potential utility for the CHW intervention, future research will investigate the impact of the intervention on caries development. This study's exploratory aim also will determine if future CHW studies need to further investigate setting of CHW intervention delivery.

CHWs typically work out of either a clinical location or a community agency. Therefore CO-OP Chicago places CHWs in both types of location as their primary base. Ten pediatric primary care clinics that serve low income families were recruited, as well as 10 Women Infant and Children (WIC) centers which are social service centers where families receive free formula and food. CHWs can meet with families in their clinic/WIC center, participant homes, or a mutually-agreed upon location. The CHW intervention will be delivered over four in-person visits within one year; this "dosage" was chosen in order to align with well child medical checks and WIC center appointments (typically every 3 months). Four visits per year has also been found in other disease areas to be both acceptable to families and associated with cost savings.[29] The one-year duration was chosen because completing dental clinic visits or making behavioral changes can take months. In addition, the CHWs often need to spend entire visits on social issues such as communication or access. These are important time investments because they allow the families to gain resources and skills to make changes related to oral health. Another advantage to a year-long intervention is that it allows for reinforcement after mastering a behavior (such as brushing daily) in order to maintain that behavior long term.

The study population was chosen for several reasons. While caries can be treated, the ultimate goal in pediatrics is primary prevention. Families with children under the age of 3 years old were chosen in order to establish healthy behaviors for a lifetime.[30] The recruitment sites serve low income, predominantly minority families whose rates of caries development are higher than the general population.[31-32]

2.3 Potential Risks and Benefits

There are no known benefits to this research. The risks are mainly related to discomfort and confidentiality, as described in Section 2.3.1.

2.3.1 Potential Risks

Caregivers and children who participate in this study may experience discomfort with responding to questions, having their home and brushing observed, and having their children's teeth examined. They may not be comfortable with research staff or CHWs in their home. Staff will assure families that individual responses to study questionnaires

and individual oral exam and behavioral observation data collected for the study will not be shared with social service agencies, organizations, and people outside the study.

There is a risk of loss of confidentiality for all study participants. Precautions will be in place to minimize this risk, such as collecting only minimal identifying information and storing data collection documents in locked cabinets (located in locked offices), using unique study codes for participants, using encrypted computers, and maintaining electronic data files on a password-protected computer drive. Individual identifier numbers that are linked to participant contact information will be stored separately from the data. Compliance with all IRB regulations concerning data collection, data analysis, data storage, and data destruction will be strictly observed.

2.3.2 Potential Benefits

All study participants will be offered oral health CHW services either during the study or after its completion; however, it has not been demonstrated to date if this is a beneficial intervention. Therefore there are no known direct benefits to study participants. This study is intended to determine the efficacy of a CHW-delivered oral health intervention, which may add to the body of knowledge about interventions that improve children's oral health.

3 OBJECTIVES

3.1 Study Objectives

The primary study objective is to evaluate the efficacy of a one-year oral health CHW intervention, compared to usual care, to improve self-reported brushing frequency and observed plaque score in low income urban children under the age of 3 years old.

The study's first exploratory aim is to determine if the oral health CHW intervention impact on child tooth brushing behaviors varies when the CHWs are based out of a medical clinic compared to a community WIC center.

The second exploratory aim is to determine the cost effectiveness of the CHW intervention compared to usual care at the system-level.

3.2 Study Outcome Measures

Outcome measures will be collected by research assistants at baseline, 6 months and 12 months. Outcomes are a mixture of self-report, clinical assessment, observations of behaviors and the home environment, and cost data. These are described in detail in Appendix B.

3.2.1 Primary

This study has two primary assessment measures of tooth brushing behavior.

(1) Caregiver self-report of child tooth brushing frequency: This is an ordinal variable (<1 time/day, 1 time/day, 2 or more times/day). The goal of the intervention is to increase the frequency of participants reporting "2 or more times/day".

(2) Dental plaque: See Appendix C for the full plaque score protocol. Using disclosing solution, plaque will be observed on the buccal surfaces of teeth #D, E, F and G. Amount of plaque is reported using the Oral health Index - Maxillary Incisor Score (OHI-MIS) which is a continuous variable, range 0 to 3.

3.2.2 Secondary

The secondary measures (shown in detail in Appendix B) are organized into several domains.

Oral health behaviors include duration of brushing and caregiver assistance with brushing, age started brushing, amount of toothpaste, and type of toothpaste (fluoride or no fluoride.) Whenever possible, self-reported behaviors will also be observed. Child access to appropriate timely dental care will also be assessed. CHWs will target all these behaviors in the intervention. In analyses, these variables will represent additional components of healthy daily oral care behaviors for children.

CHWs work by improving knowledge, self-efficacy, and building self-management skills and supports.[14-16] Therefore we will measure caregiver knowledge, self-efficacy, and child and caregiver oral health quality of life. We will also measure caregiver psychological functioning, social support, and family functioning using the NIH PROMIS measures and the CHAOS scale.[33-36] These variables will be used in analyses to understand changes, or lack of, in the primary outcomes.

A range of risk factors for caries and associated oral health behaviors will be measured as covariates. These include exposure to sugar sweetened beverages, weaning behaviors, prior caries experience, sibling severe caries experience, and caregiver oral health behaviors and access. Medical risk factors such as child co-morbidities, medications, and weight will be assessed.

Data will also be collected on the CHW intervention, both to inform intervention fidelity and generate cost estimates. Cost estimates are only relevant for the CHW intervention arm, because the usual care arm has no additional costs. Cost estimates will only be collected on the system-level. While individuals may ultimately incur some costs, the intervention is designed to minimize these. (Visits in clinics and WICs will be aligned with visits they already plan to attend for healthcare or WIC services. Home visits will be arranged around work schedules and require no travel for participants.)

> System-level costs: CHW time for visit set-up, travel, and delivery will be determined. Duration of CHW visits will be recorded (using case report forms), as well as the time needed for scheduling (weekly estimates with supervisor) and for transportation to home visits (mileage logs). This will be multiplied by CHW salary/benefits. The mileage costs will be recorded from mileage logs. CHW supplies and equipment (educational materials, phones, computers, and any other items) will be obtained through expense reports.

4 STUDY DESIGN

- CO-OP Chicago is a two-arm cluster randomized controlled trial with repeated measurements. The comparison arm receives usual care. (After completion of the trial, the usual care arm will be offered limited CHW intervention.) The nature of the intervention allows for a single blind design in which data collection will be performed by research assistants.
- The trial targets healthy, low income, predominantly minority children under the age of 3 years old, and their families in Cook County, Illinois.
- This is a multi-center trial with two arms and 20 sites (clusters).
- We will recruit between 18-23 families from each site for a total sample size of 420. Sites are in two strata: medical clinic and WIC. These are combined for the primary analysis but will be compared to each other in the exploratory analysis.
- Study enrollment is scheduled to be completed in approximately 12 months. The primary recruitment will occur in the first 10 months, and the last two months will allow for unexpected delays.
- Participants will undergo study procedures for 12 months (+ 3 months).
- Participants will be recruited from each of the 20 study sites. Once recruitment at a site is completed, the site will be randomized and participants will be informed of the arm allocation. Participants assigned to the CHW arm will then be offered four CHW in-person visits and four follow-up phone calls over 12 months. The expectation is that in-person visits will align with well-child checks/WIC appointments every 3 months, so two visits in the first six months and two visits in the second six months, although the schedule is flexible. Telephone follow-up calls will follow in-person visits at a time determined meaningful by the CHW and family. Participants assigned to the usual care arm will be offered a CHW visit after they complete the final data collection at 12 months.
- Screening will occur at the study sites during the recruitment phase. Initial screening will be conducted verbally. Caregivers who are interested in participating will have an enrollment data collection visit scheduled. The study staff (two RAs) will conduct this visit in the family's home, at the recruitment site, or at another mutually agreed upon location. First, consent will be obtained. Then the staff will obtain survey responses by verbally asking questions about demographics, brushing, general health, social support, access to care, and health behaviors. Child dental plaque measurements will be obtained: disclosing solution will be applied to the child's teeth and the teeth will be photographed. If the data collection is occurring in the home, families will be asked to demonstrate tooth brushing and the technique and equipment will be documented. Data will be collected again by RAs at 6 months and 12 months.

- After sufficient participants have been enrolled from a site, the site will undergo randomization procedures. If the site is randomized to CHW services, all participants enrolled at that site will be offered the CHW intervention.
- Outcomes will be collected via self-report, clinical assessment, and observation of behaviors and equipment. This is described in detail in Section 3.2. Plaque will be captured via photographs in the field which will then be scored by a calibrated clinician at UIC.

5 STUDY ENROLLMENT AND WITHDRAWAL

5.1 Subject Inclusion Criteria

To be eligible to participate in these study activities, the caregiver/child dyad must meet the following criteria:

Caregiver:

- Provide a signed and dated informed consent form
- Age 18 or older
- Be the primary caregiver of a child age 6-36 months old. The primary caregiver is defined for this study as the person (or one of the people) who is consistently responsible for the child's daily routines and who is a legal guardian.
- If a child lives in multiple households, the caregiver must live with the child at least 5 days of the week.
- The child must be an active patient/client in the clinic/center where recruited.
- Speak English or Spanish
- Willing to comply with all study procedures and be available for the duration of the study

Child:

- Age 6-36 months old
- An active patient/client in the clinic/center where recruited
- A minimum of two fully erupted central maxillary incisors

5.2 Subject Exclusion Criteria

A caregiver/child dyad who meets any of the following criteria will be excluded from participation in this study:

- Child with medical condition that limits his or her ability to conduct the study activities (such as severe developmental or cognitive delay, ventilator or oxygen dependence, oral aversion, severe facial deformities)
- Anything that would place the individual at increased risk or preclude the individual's full compliance with or completion of the study
- Anything that would place the research or intervention staff at increased risk

5.3 Strategies for Recruitment and Retention

This trial will recruit a total of 420 caregiver/child dyads, 18-23 dyads from each of the 20 sites. In the CO-OP Chicago Pilot, 123 caregivers were approached, 58 agreed to participate, and 20 completed the enrollment. This suggests a screening to enrollment ratio of 6:1. Patient/client volumes vary by site, but the 20 sites together comprise at least 2400 potentially eligible subjects. Similar to the pilot, the RAs will approach

caregivers of young children who seem to be under the age of 3 in the waiting area of the clinic/center. The RA will assess the caregiver interest in the study and review inclusion/exclusion criteria. If the caregiver expresses a willingness and interest in study procedures, the RA will obtain caregiver's contact information and schedule an enrollment appointment. It took RAs about 3 hours of screening time for each enrolled family in the pilot. Families are given small incentives like toothbrushes for completing the screening.

Consent procedures will be conducted at the beginning of the enrollment visit, and the visit should last no more than 60 minutes. At the completion of the visit, participants will be offered $40 and a flyer describing basic oral health tips (https://www.nidcr.nih.gov/oralhealth/Topics/ToothDecay/Documents/healthy-mouth-for-your-baby-factsheet.pdf.)

Once enrolled, participants will be contacted again by RAs at 6 months and 12 months for data collection. Payment will be the same at those visits ($40). In total, families that complete all data collections will receive $120.

The contact procedures are detailed in Appendix D. Retention for all participants will be achieved by:

- Careful vetting of all research materials through a community advisory board to ensure participants feel connected to the trial;
- Using field staff who are engaging, respectful, and non-threatening;
- Collecting multiple types of contact information for participants including primary phone, back up phone, emails, address, back up address, and an alternative contact person's phone and address. RAs will clarify at each contact timepoint how participants prefer to be contacted (text, email, phone call) and when are the best times to reach them;
- Remuneration for data collection;
- Maintaining strong partnerships with the participant's clinic/WIC center.

Participants might experience a delay between enrollment and randomization while waiting for site to reach sufficient enrollment numbers. While waiting for randomization, research staff will call the family to verify contact information and reassure them about the study every 4 weeks.

5.4 Treatment Assignment Procedures

Participant treatment assignments are determined by their site of enrollment. Sites will be cluster randomized to CHW or usual care. This process is described in Section 5.4.1.

5.4.1 Randomization Procedures

Clinic and WIC sites will be randomized on the site level once enrollment has reached approximately 90% of goal (18-23 families) at each site. Simple cluster randomization with relatively small numbers of clusters is susceptible to baseline imbalance with

respect to cluster and participant characteristics between the intervention and comparison conditions. Thus, restricted randomization of clusters is commonly employed to enforce greater balance, which both eliminates potential bias and enhances power. We are using terminology from the review paper by Noah Ivers et al. where minimization and covariate-constrained randomization are special cases of a more general category of restricted randomization.[37] We will employ a stratified by clinic/WIC minimization method to ensure baseline characteristic balance at both cluster and participant level. Randomizing sites after approximately 90% of the enrollment goal will ensure blinding of RAs, site staff, and participants until most participants from each site are enrolled. (The last 10% of participants are often the slowest to recruit and this small number should not influence the participant-level covariate balance.) Cluster-level summary statistics regarding race and ethnicity characteristics of the site population (African American, Latino, or mixed) and site size (high, medium, low) will be used as cluster-level covariates for minimization. Cluster-level randomization will be done by the UCSF Coordinating Center (CC). Once a site is randomized, the CC will inform the UIC project manager who will inform the site leadership of the site assignment via email and/or phone call. The UIC project manager will assign a CHW if randomized to that arm. The project manager will then inform the CHW of his/her participants and provide access to their contact information. UIC will send letters via mail to participants informing them of their site's assignment, and their CHW's information if applicable.

5.4.2 Masking Procedures

Although double blinding in a behavioral randomized clinical trial is not feasible, blinding will be maximized by utilizing independent outcomes assessors (research assistants) who will be blinded to study arm, and by reminding staff and partners about equipoise. Participants will be reminded at every contact to not disclose their study arm or any intervention they are or are not receiving. Investigators who supervise the CHWs and the project manager will be unblinded to treatment arm because they will need to work with the CHWs and monitor intervention fidelity and data accuracy. The USCF CC will also be unblinded to treatment arm. Study staff and investigators will not have access to interim outcomes data. Unmasking procedures are described in more detail in the Manual of Procedures.

5.5 Subject Withdrawal

Subjects may voluntarily withdraw their consent from the study.

5.5.1 Reasons for Withdrawal

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

5.5.2 Handling of Subject Withdrawals or Subject Discontinuation of Study Intervention

If a participant requests to be withdrawn from the study, the following must happen for official withdrawal:

- Principal Investigator (PI) calls and/or emails to explain instructions for withdrawal
- Mail/email them a copy of their signed consent along with letter from the PI and stamped envelope addressed to UIC/IHRP that includes instructions on how to withdraw
    - If no response in 2 weeks, repeat mailing
- Instructions
    - Participant caregiver to write “I am withdrawing from this study” somewhere on the consent form and send it back in the envelope provided.
- If no response or returned consent form, participant remains in study. Continue to repeat procedure if participant continues to request withdrawal.
- Once a participant is withdrawn, a note should be placed in their clinic/WIC records stating this.

Families that withdraw will not be replaced.

5.6 Premature Termination or Suspension of Study

This study may be suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to Dr. Molly Martin, funding agency, and regulatory authorities. 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 that are not sufficiently complete and/or evaluable.
- Determination of futility.

6 STUDY INTERVENTION

6.1 Study Behavioral or Social Intervention(s) Description

This study will test an oral health CHW intervention.

6.1.1. CHW Intervention Pedagogy

CHWs use social cognitive theory to help families shape and maintain behaviors.[38] The CO-OP Chicago Oral Health CHW intervention will apply formal self-management skills (problem solving, decision making, resource utilization, patient/doctor partnership, and taking action),[39-442] in addition to the oral health core curriculum. CHWs will use Action Plans as a tool to teach these skills and take action. Action Plans are small goals for a specific change over a designated time period (Appendix E). The CHWs will start by providing education from the oral health core curriculum, but when they note a barrier in the delivery of the education, they will incorporate a relevant self-management skill and create an action. For example, a CHW may suspect the family is not brushing the child's teeth regularly but instead of just saying that, the CHW will have the family track how often the child is brushing over a one week period. The family will "self-discover" they do not brush as often as recommended. Then the CHW will have the family brainstorm as to why that might be (bathroom organization, parent work schedules, behavioral issues, etc.). Once they have a list of the problems, the family will create an Action Plan for one problem they want to work on. On subsequent CHW visits and follow-up telephone calls, CHWs revisit past Action Plans, revise them, and make new ones.

6.1.2. CHW Core Curriculum

1. Oral health basics
    a. What is caries
    b. Causes of caries
    c. Importance of caries prevention
2. Tooth brushing
    a. When to start
    b. Frequency
    c. Technique
    d. Equipment
    e. Toothpaste
3. Fluoride
    a. Water
    b. Other sources
4. Weaning
    a. When to transition from bottle
    b. Sippy cup recommendations
    c. Nighttime feeding
5. Nutrition
    a. Sugar-sweetened beverages
    b. Juice
    c. Healthy foods
6. Seeing the dentist
    a. When to start
    b. What to expect
    c. Frequency
    d. Role of the pediatrician

6.2 Administration of Intervention

Families will be offered 4 in-person visits and 4 phone call follow-ups over 12 months. The expectation is that two visits will occur in the first six months and two visits will occur in the second six months. The expectation for phone call follow-ups is that they will occur after the in–person visits, on a schedule that is determined by the family and CHW. Visits can occur at any location of the family's choosing. This could be the home, clinic, WIC, or other location.

At in-person visits, CHWs will spend 1-2 hours with the family. The first 15 minutes are spent in social engagement (getting to know the people in the family and the family's interests, as well as the family getting to know the CHW, or catching up socially if families are already known). CHWs will try to engage all family members in the visits if possible. At the first visit, the CHW will then administer the Caries-risk Assessment Tool[43] (Appendix F) for all family members present. CHWs will follow this with tailored education based upon the risk assessment results using a variety of live demonstration, pictorial, video, and written resources. The oral health topics are drawn from the Core Curriculum (Section 6.1.2, Appendix G). CHWs will generally apply popular education methods[44], meaning they will rarely use written materials. Instead they will engage the family in discussion using questions, stories, videos, and demonstrations. These are the same techniques and methods used in the CHW training. For equipment, CHWs will have computers with Wi-Fi access (via hotspots) to view videos. CHWs will have models for demonstrating tooth brushing and they will practice with families. CHWs will also facilitate family-wide dental care access by identifying accepting providers, providing families with provider contact information, and assisting to make appointments as needed. CHWs will have access to Purple Binder which is an online community resources search service (www.purplebinder.com). For the last 15 minutes of the visit, families will make Action Plans (Appendix E). At the start of all subsequent visits, Action Plans from the previous visit will be reviewed and discussed. CHWs will aim to address all the core curriculum topics over the one year intervention. After each visit, CHWs will call or text the caregiver during the subsequent month to follow-up on actions and reinforce concepts from the previous visit. The detailed core curriculum protocol and materials are included in Appendix G. CHWs will document topics covered and materials used immediately after each visit. (Form in Appendix H). Follow-up telephone calls will be conducted to review information and plans, address questions, and provide social support. (Appendix G)

6.3 Procedures for Training Interventionists and Monitoring Intervention Fidelity

6.3.1. CHW Training and Hiring

Because limited formal certification or licensing programs for CHWs exist nationally or locally,[45] training curriculums are developed for individual programs and are not standardized for any disease area. CHWs require training in disease-specific content,

building relationships, self-advocacy, teamwork and conflict resolution, crisis and emergency management, and home visitation before going into the field.[13,45]

Phase I: Pre-Hire Training

Potential candidates for the CHW positions will be recruited through existing UIC programs, participating medical clinics and WIC sites, community list-serves, and word of mouth. Preference will be given to candidates who have already worked as CHWs and who have experience with the participating clinics or WIC centers. We plan to hold one training session on the west side and another on the south side of Chicago. Notices for the training will be distributed through the partner sites, UIC, and local CHW listserves. A cohort of 12-15 candidates will be selected from those who express interest to attend each pre-hire training. Pre-hire training serves several purposes: 1) The training builds community capacity and skills around oral health, 2) It allows investigators to determine the best candidates for the position, and 3) It provides a pool of back-up candidates for the future. In the pilot phase of this project, the CO-OP Chicago team built and tested a comprehensive oral health CHW training curriculum.[28] The manual is available at website (*http://go.uic.edu/COOPChicago*) and in the Manual of Procedures. This 4.5 hour training will be conducted by Dr. Martin and either Dr. Avenetti or the hygienist in English. The training concludes with standardized role plays to evaluate skills attainment and content delivery. Once both trainings are completed, the CHW positions will be posted, and trainees will be invited to apply. The training role play scores and observations will be compared. The best candidates will be interviewed and hired. Additional pre-hire trainings will be conducted if needed until the CHWs are hired.

Phase 2: Post-Hire Training

Three to four CHWs (3.0 FTE) will be hired. Once hired, CHWs will undergo additional training. If the CHWs have not previously worked or been trained as CHWs, they will undergo the UIC Coordinated Healthcare for Complex Kids (CHECK, *https://www.mycheck.uic.edu/* basic CHW training which was designed by Dr. Martin and is supervised currently by Dr. Minier:

CHECK Basic CHW Training Program

Topics	Duration
CHECK Overview: Medicare and Medicaid overview, CMS innovations awards, Inappropriate healthcare use, Goals and activities of CHECK	1 hour 30 minutes
Health and Disease Overview: Diabetes type 1, Prematurity, Sickle cell disease, Asthma	1 hour
Building Relationships and Motivational Interviewing: Trust, Communication, Coping and support, Respect and patient-centeredness	1 hour
Self-Advocacy: Advocating for yourself, teaching patients to self-advocate	30 minutes
Teamwork and Conflict Resolution: Teamwork, Conflict resolution	30 minutes
Managing Transitions: Transitioning from adolescence to adulthood, Transitioning from pediatric to adult care, Hospital to home	30 minutes

Home Visitation: Why home visits, Preparing for a home visit, Safety, Home visit etiquette, Building trust, Mandatory reporting	1 hour
Self-Management: Problem solving, Social support, Environmental rearrangement, Self-monitoring, Action planning	1 hour
Operations: Office tour, Supplies (obtain laptop, office supplies, keys, office space, business cards, parking card), Building access, Job description, Job management (evaluations, monitoring, union, hours, scheduling, payroll, meetings, supervision)	3 hours
Teams and Protocols: Geographic zones/teams, Mobile van/dentistry, Phone protocols, Assessment protocols, Mental health specialists, disease specific teams (asthma, diabetes, sickle cell disease, prematurity), Hospital protocols, Tour	4 hours
Insurance: Medicaid managed care companies, Medical neighborhoods	1 hour
Community Outreach Basics of community outreach**,** Community-based medical neighborhood**,** Tour	1 hour 30 minutes
Medical Legal Issues: Medical legal team, Social Security, Education issues (504 plans and Individual Education Plans)	1 hour
Technology: Data access, use, and support; Purple binder; Compliance and HIPAA	2 hours

CHWs will be familiarized with the study protocol, clinic and WIC site policies, home visitation strategies, and documentation. CHWs will complete the 12-hour Mental Health First Aid course (*www.mentalhealthfirstaid.org*). Dr. Raja will then teach and practice basic motivational interviewing (4 hours). CHWs will shadow experienced CHWs on other projects at UIC for a minimum of three visits and they will shadow UIC dental clinicians for a minimum of 20 hours before being ready for field work. The first three CHW home visits will be conducted with the CHW supervisor. The CHW supervisor will score each visit using the CHW Fidelity Assessment Form (Appendix I). When the CHW scores at least 4 in each category on three visits, the CHW is ready to visit participants alone.

Phase 3: Ongoing Training

CHWs will receive continual education that includes monthly reviews of topics of interest to the CHWs, as well as participation in general CHW events conducted by the Chicago CHW Local Network (*http://chwnetwork.wordpress.com/*) and the CHECK Care Coordination team. Continual education includes oral health topics as needed (see Section 6.3.3.)

6.3.2. CHW Supervision

CHWs are not clinicians and they often struggle with many of the same issues as their clients in terms of health problems, children, housing, and poverty. This allows them to intimately understand the challenges their clients face and usually translates into strong bonds between CHWs and clients, but it sometimes transforms into a significant burden when clients struggle with serious issues. The CHWs also must deal with the stresses of home visitation (safety, cleanliness, hectic households, and poverty) and the pressures of executing a new non-clinical role in clinical and WIC settings. In order for CHWs to successfully perform their job, they require adequate supervision and support. Supervision is best conducted using a team approach with a group of CHWs to facilitate

self-discovery and group learning. In CO-OP Chicago, CHWs will report directly to the CHW supervisor (the CO-OP Chicago project manager) for day-to-day supervision and support. Dr. Minier and the project manager will ensure the CHW roles are properly explained to clinical staff and faculty in the participating clinics. Ms. Pinkwater will provide a similar role within the WIC sites. CHWs will meet with the CHW supervisor weekly. Every two weeks, CHWs will also meet with the CHW supervisor, Dr. Martin, Dr. Avenetti, and Dr. Martin/Ms. Pinkwater (rotating) for discussion of clinical issues, self-management skills support, and for continuing education. Dr. Raja will meet with CHWs on an as-needed basis to discuss mental health issues related to participants or the CHW job and to generate strategies for resolution.

6.3.3. Fidelity Monitoring

CHWs will have a caseload of up to 70 patients, each of whom will receive 4 visits and follow-up calls over one year. CHWs will complete documentation after every encounter to record visit location, duration, oral health curriculum topics covered, resources utilized, issues encountered, and family members who participated. This form is in Appendix I. These data will be reviewed monthly by the CHW supervisor and investigators to ensure consistency and fidelity of the intervention content and also to inform the study team about areas of focus and challenge. Reports from these data will show core curriculum topics covered and pending per patient, resources used, and overall trends in topics. While the goal is to cover each of the core curriculum topics over the duration of the intervention with each family, CHWs may deviate due to family needs and resources. Deviations will be reviewed; if they are due to CHW issues (lack of comfort with a topic or poor organization), additional training will be provided either to the specific CHW alone or to the group as needed. These data will also be used in final analyses to determine “dose” of intervention and assess the influence of specific topics/skills on outcomes.

The CHW supervisor will accompany each CHW on a minimum of one visit out of every 30 (8% of total visits). The CHW supervisor will assess the CHW using the CHW Fidelity Assessment Form (Appendix I). If a CHW scores less than 4 on any category, additional training and support will be provided to the CHW. Depending on the specific issue, additional training/support could include extra sessions with the investigators, and/or more shadowing experience with more experienced CHWs and/or in the dental clinic. Additional visit supervision and fidelity scoring will be implemented until the CHW is consistently scoring 4 on all categories.

6.4 Assessment of Subject Compliance with Study Intervention

Subject compliance is defined and measured in two ways. First, we will measure compliance with the CHW visit protocol, meaning how many of the four in-person visits and two follow-up phone calls are completed in the 12-month intervention period. This is assessed using the CHW documentation (number of visits/calls completed). Families that are not compliant will have less CHW encounters. Second, we will monitor participant compliance with goals. This is determined using the Action Plans (Appendix

E) that are completed at each in-person visit. The Action Plan documents record the goals and the CHW Encounter Tracking Form (Appendix H) records progress, or lack of, regarding these Action Plans (goal achieved, partially achieved, or not achieved at all).

7 STUDY SCHEDULE

7.1 Screening

Screening Visit with RA (prior to Baseline Visit)

- Obtain and document verbal consent from potential caregiver subject on screening consent document.
- Ask the potential caregiver subject screening questions to determine eligibility.
- Perform brief visual examination needed to determine eligibility of the child subject.
- Describe the study procedures and show the recruitment video (if interested).
- Schedule study enrollment visit for individuals who are eligible, interested, and available for the duration of the study.

7.2 Enrollment/Baseline Visit with RA (Visit 1, prior to Randomization)

- Obtain and document consent from subject on study consent form.
- Verify inclusion/exclusion criteria.
- Obtain self-reported data via verbal questionnaire. This includes demographic information, oral health behaviors, oral health risk factors, medical history questions, and family psychosocial functioning.
- Weigh child.
- Apply disclosing solution to child’s teeth and obtain photographs for plaque assessment.
- If conducted in home, observe child brushing teeth and brushing equipment.
- Explain to family the randomization process and when intervention will start (Intervention will begin after randomization for families in sites that are randomized to receive CHW services. For families in sites that are randomized to not receive CHW services, they will be offered CHW services after study completion in one year.)
- Verify contact information.
- Thank family. Offer remuneration and give flyer on basic oral health recommendations.

7.3 Randomization, Day 0

Each site will be randomized to CHWs or usual care once recruitment is completed or near completion. See Section 5.4.1. for details.

7.4 Intervention in-person visits for CHW-sites only, start Day 1 and complete by Day 365

Four in-person visits will be offered to families. See Appendix D for details. The first two visits will be delivered between days 1-179. The third and fourth visits will be delivered between days 180-364.

7.5 Intervention telephone follow-ups for CHW-sites only, start Day 2 and complete by Day 365

Four follow-up telephone calls will be offered to families. The plan is for follow-up telephone calls to follow in-person visits.

7.6 6-Month Visit with RA, Day 180 (- 14 days, + 60 days)

- Obtain self-reported data via verbal questionnaire. This includes demographic information, oral health behaviors, oral health risk factors, medical history questions, and family psychosocial functioning.
- Weigh child.
- Apply disclosing solution to child's teeth and obtain photographs for plaque assessment.
- If conducted in home, observe child brushing teeth and brushing equipment.
- Record adverse events as reported by subject or observed by investigator.
- Verify contact information.
- Thank family. Offer remuneration.

7.7 Final Study Visit with RA, Day 365 (+ 90 days)

- Obtain self-reported data via verbal questionnaire. This includes demographic information, oral health behaviors, oral health risk factors, medical history questions, and family psychosocial functioning.
- Weigh child.
- Apply disclosing solution to child's teeth and obtain photographs for plaque assessment.
- If conducted in home, observe child brushing teeth and brushing equipment.

- Record adverse events as reported by subject or observed by investigator.
- Remind family that we will send families a copy of the study results at the end of the study. Results will also be posted on the study website and displayed at the clinic/WIC center. Remind families that if they are in the usual care arm, they will soon receive a phone call from a CHW offering them a visit. Remind them that we may contact them in the future for follow-up studies if they agreed to that at the time of consent. Verify contact information.
- Thank family. Offer remuneration.

7.8 Intervention in-person visits for usual care-sites only, start Day 1 after final day collection and complete end of study

Families that are in usual care sites will be offered one CHW visit after they complete the final data entry. This is a courtesy visit to assess family risks and refer them to existing resources. The window for completion of this visit will last as long as funding is available for the CHWs.

7.9 Withdrawal Visit

If a subject withdraws from the trial or is administratively withdrawn, no more data collection will occur.

8 STUDY PROCEDURES /EVALUATIONS

8.1 Study Procedures/Evaluations

Location

Because data collection would ideally occur in the homes by RAs, the home will be presented to families as the preferred location. Families that agree to home data collection will be given first priority in enrollment. Some families may be uncomfortable with home data collection for a variety of reasons including trust, not being on the lease at the place they live, or feeling that the home is unclean or unsafe. Families that want to participate but cannot agree to a home visit will be scheduled for data collection in their site of recruitment (WIC or clinic) or another location where the plaque measurement can be performed. Once families have interacted with project staff and better understand the study, they may agree to future data collection and intervention visits in the home. For the 6- and 12-month data collection visits, home will again be the preferred location for data collection, though collection of the study primary outcomes is the most important factor regarding data collection location.

Survey development

Most survey questions were drawn from NHANES, NHIS, and the previous EC4 consortium, or are published survey instruments. A few questions were developed by the CO-OP Steering Committee to capture variables of interest for this research. The questions and question sources are shown in Appendix B. Primary domains are brushing behaviors, oral health risk factors, and demographics. These questions were informed by the clinical expertise of the investigators as well as the investigators' experience doing home environmental assessments for research purposes.[46-47]

Data Collection

All instruments will be in the preferred language of the caregiver. The RA will verbally ask study questions to the participants, using visual prompts to show response options. The RA will record answers on a portable laptop computer unless Wi-Fi is not available or the computer malfunctions, in which case paper forms will be used. An exception to this are the questions from the PROMIS scales. The RA will administer the PROMIS questions in the same way as the other questions with one exception; if the environment does not seem to offer sufficient privacy or the caregiver seems reluctant to verbally answer these questions, the RA will offer the caregiver the option of completing the questions on the computer (handing the computer to the participant to complete) or on a paper version with pen/pencil. The decision between computer or paper will be made based on the respondent's comfort with computers. Our experiences in similar populations and in the pilot phase of this project have suggested that the reading ability of many adults is limited, and they usually are more comfortable when they are read the questions, even when the questions are sensitive. The PROMIS depression, anxiety,

and functioning scale is not a clinical tool and does not have a clinical cut point that requires action.[35-36] RAs will offer a list of mental health resources to all participants at the conclusion of the PROMIS questions.

Next, the following procedures will be performed:

Plaque measurement: A RA will apply disclosing solution to the anterior maxillary incisors while another RA photographs the teeth. The images will be verified for accuracy. A dental hygienist or dentist will obtain a plaque score from the photographs, following the Simplified Oral Hygiene Index - Maxillary Incisor (OHI-MIS) described by Greene and Vermillion.[48] The detailed protocol is in Appendix C.

Tooth brushing observation: The RA will observe the child's tooth brushing, including any caregiver assistance with this activity and the equipment used for brushing. The RA will document the steps of brushing, caregiver involvement in the process, the time of active brushing, and equipment used.

Data fidelity

The UCSF Coordinating Center (CC) is developing a gold standard calibration protocol for examiners of plaque. This will include the specific requirements of images and will ensure scoring of images is consistent. (Also see Section 14). RAs will practice application of the disclosing solution and image obtainment under the supervision of study investigators until they demonstrate they can consistently collect quality images for scoring. They will then review the plaque measurement procedures monthly with investigators.

RAs will practice collection of all questionnaire and behavior observation data, and then two RAs will simultaneously collect data (double data entry) from practice participants (and sometimes real participants) until 95% concordance between RA-collected data is observed. The RA field supervisor will then observe and double code one out of every 30 data collections to ensure fidelity. If errors are noted or concordance is less than 95%, the RA will be required to practice additional data collection under the supervision of the field supervisor until 95% concordance is achieved.

9 ASSESSMENT OF SAFETY

9.1 Specification of Safety Parameters

Safety monitoring for this study will focus on unanticipated problems involving risks to participants, including unanticipated problems that meet the definition of a serious adverse event.

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.

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

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 will be recorded in the data collection system throughout the study.

The PI will record all events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study visit, the investigator will inquire about the occurrence of AE/SAEs since the last visit. 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

The Study PI will be responsible for determining whether an SAE 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 IRB and NIDCR

Incidents or events that meet the OHRP criteria for unanticipated problems require the creation and completion of an unanticipated problem report form. OHRP recommends that investigators include the following information when reporting an adverse event, or any other incident, experience, or outcome as an unanticipated problem to the 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 IRB and to NIDCR within 5 business days of the investigator becoming aware of the event.
- Any other unanticipated problem will be reported to the IRB and to NIDCR within 15 business days of the investigator becoming aware of the problem.
- All unanticipated problems should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting

agency head (or designee), and OHRP within one month of the IRB's receipt of the report of the problem from the investigator.

All unanticipated problems, including unanticipated problems that are SAEs, will be reported to NIDCR through the Rho Product Safety centralized reporting system :

- Product Safety Fax Line (US): 1-888-746-3293
- Product Safety Fax Line (International): 919-287-3998
- Product Safety Email: rho_productsafety@rhoworld.com

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

- US: 1-888-746-7231
- International: 919-595-6486

For any unanticipated problem meeting the SAE criteria, the study clinician will complete a Serious Adverse Event Form and will submit via fax or email within the timelines stated in Section 9.4.1. Once submitted, Rho Product Safety will send a confirmation email to the investigator within 1 business day. The investigator should contact Rho Product Safety if this confirmation is not received. This process applies to both initial and follow-up SAE reports.

10 STUDY OVERSIGHT

In addition to the PI's responsibility for oversight, study oversight will be under the direction of a Data and Safety Monitoring Board (DSMB) composed of members with appropriate clinical, statistical, scientific, and ethical expertise. The NIDCR will appoint the Board. The DSMB will meet annually to assess safety and efficacy data (if applicable), study progress, and data integrity for the study. If concerns arise, more frequent meetings may be held. The DSMB will operate under the rules of an NIDCR-approved charter that will be approved at the organizational meeting of the DSMB. The DSMB will provide recommendations to the NIDCR.

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/Project Scientist. 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

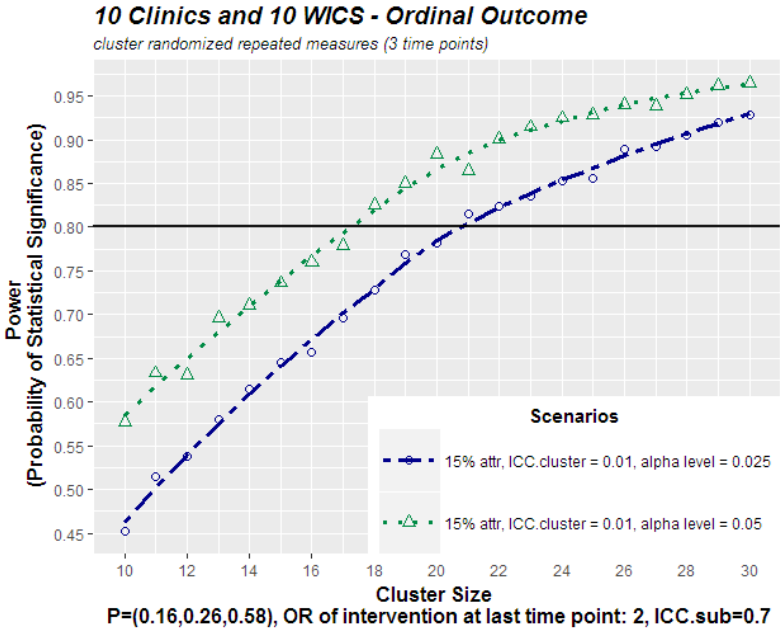
12.1 Study Hypotheses

The primary hypothesis this study tests is as follows: Participants receiving the oral health CHW intervention will have improved oral health behaviors, as measured using self-reported brushing frequency and observed plaque score, at 12 months compared to participants receiving usual care.

12.2 Sample Size Considerations

Study design: 10 clinics and 10 WICs, cluster randomized allocation to two arms.

Brushing frequency: Brushing frequency is an ordinal variable with three categories: <1 a day, once a day, 2 or more times a day measured at baseline, 6 months, and 12 months. The proportion of responses (from the pilot study) in the reference population is p0 = (0.16, 0.26, 0.58). We assume cross-time correlation due to repeated observations is 0.7, which is a reasonable assumption for behavioral outcomes. We assumed the interclass correlation (ICC) due to clustering in sites is 0.01. (Using CO-OP UH2 pilot data, the ICC was 0. When 3 sites were added to these data, the ICC was still 0. This may simply reflect a small sample size. Alternatively the ICC due to site clustering may be so small as to be negligible. Therefore, we feel 0.01 is a conservative assumption.) We also assumed the effect size of 2 between arms at the study endpoint expressed as OR. This effect size translates to the following proportion of frequency of brushing in the intervention arm: p1 = (0.09, 0.18, 0.73).



The power calculation used Monte Carlo simulation based on 1000 datasets (see below for details). We used a proportional odds model in the power simulation. To achieve power of 80%, we will need to recruit 21 participants from each cluster (420participants total). The sample size calculation controls for multiplicity of having two outcomes measures by Bonferroni adjustment (Type 1 error = 0.025). The proposed sample size is a conservative estimate as the simulation does not take into account stratification due to clinics and WICs. The analysis will control for outcome imbalance between clinics and WICs via covariate adjustment and hence increase precision of the estimates.

Data Generating Model for Power Simulation

We followed a mixed-effect ordinal logistic model motivated by an underlying latent variable.[49] The three-level data structure was defined as follows. We assumed that there are $k = 1,...,n_{ij}$ level-1 units that are nested within $j = 1,...,n_i$ level-2 units that are, in turn, nested within $i = 1,...,n$ level-3 units. In the case of our longitudinal cluster-randomized trial, the level-1 observations are the measurement occasions, level-2 corresponds to subjects, and level-3 corresponds to sites. Assuming a logistic response function for outcome with $c = 1...,C$ ordered categories, the three-level mixed effect model for the cumulative probability of a response is given by

$$\log \frac{P_{ijkc}}{\left(1 - P_{ijkc}\right)} = \gamma_c - \left(\beta_1 G_i + \beta_2 T_{ijk} + \beta_3 G_i T_{ijk} + \upsilon_{ij} + \upsilon_i\right)$$

To identify the model, we set the intercept to zero and estimated $C-1$ threshold parameters. Here, $P_{ijkc} = \Pr\left(Y_{ijk} \le c\right)$ is the probability of a response falling within the *c* lower categories. With respect to the random effects, it was assumed that the level-2 random intercept (i.e., subject-specific intercept) was normally distributed as $\upsilon_{ij} \sim N\left(0, \sigma_2^2\right)$ and the level-3 random intercept (i.e., cluster-specific intercept) was $\upsilon_i \sim N\left(0, \sigma_3^2\right)$. The random components were assumed to be independent from each other. For the fixed effects the parameter β_1 represents the intervention effect at baseline (set up at zero), and the parameter β_2 represents the slope associated with the time effect in the control group. Finally, the intervention-by-time parameter, β_3, the effect of primary interest, represents the difference in slopes for the outcome between the intervention groups.

Plaque score: Plaque score is described using the Simplified Oral Hygiene Index - Maxillary Incisor (OHI-MIS). Our sample size calculation is based on a statistical calculation of power using an effect size = 0.40 for the two arm comparison at the end of study. Our estimates of baseline OHI-MIS scores from the pilot study (mean=1.2, SD=0.78) suggest this effect size corresponds to a change of 0.31 units between arms. In order to detect this "moderate" effect size, with two-sided Type I error α = 0.025 (Bonferroni correction due to multiplicity) and Power = 0.80, each arm should have 141 participants, for a total of 282. Calculations employed Rochon's 1998 GEE method, as implemented in the SAS GEESIZE v. 3.1 macro implemented by Dahmen, et al.[50] We assumed 0.7 ICC due to repeated measures. To further account for the clustering effect due to site (ICC=0.01), the minimum needed sample size to recruit is 170 per arm or 340 total.

Both sample calculations assume 15% attrition at each follow-up (6- and 12-months).

12.3 Final Analysis Plan

The primary study objective is to evaluate the efficacy of a one-year oral health CHW intervention, compared to usual care, to improve self-reported brushing frequency and observed plaque index in low income urban children under the age of 3 years old.

Modern best practice for multilevel data is generalized mixed-effect models with random parameters to account for repeated measurements and clustering in sites.[50-52] For frequency of brushing, we will employ a random-effect ordinal regression model. The OHI-MIS will be analyzed as continuous outcome using a linear random-effect model. (Although each surface is scored ordinally, the Central Limit Theorem says that a mean - even of 4 within person measures - in a sample size of at least 25 follows the Normal [Gaussian] distribution.[53]) The model specification that follows pertains to both outcomes. The between-subjects factors – usual care or CHW, within-subjects occasions of measurement -- time, and their interaction will be in the model. The interaction term is the focus of the analysis. We will employ Bonferroni-Holm adjustments to control for multiplicity, which is a sequentially rejective procedure that provides a more powerful test than the Bonferroni correction.[54] For this, the smallest of the two outcomes p-value will be compared to 0.025, and if rejected the second p-value will be compared to 0.05 to claim significance. Fixed effect indicators for clinic and WIC sites as well as all other variables used in restricted randomization will be included in all models. Guidance specific to cluster-randomized trials will be followed.[55-57] The analysis will be carried out under intention-to-treat (ITT) principles, implying that respondents who are randomized must be represented in analysis and therefore have missing data imputed.[58] We anticipate data missing at random (MAR)[59], but will be vigilant for data not MAR (NMAR) as well. Imputation methods adapted for cluster-randomized designs will also be employed.[60-62]

Analysis of the exploratory aim with the hypothesis of no difference between sites will extend models described above with a three-way interaction: time by group by site. The analysis will follow standard mixed model approaches described in Hedeker & Gibbons.[63] We will estimate the intervention effect (average change in the outcome) at the last follow up conditional on site type. The 95% confidence interval (CI) of site difference in the estimated means will be compared to a pre-specified acceptance criterion (scientifically justified maximum difference of no clinical significance). If the 95% CI is contained within the acceptance criteria, the equivalence between sites can be declared (based on two one sided tests (TOST) approach).[64]

The cost data will first be summed and presented on the system-level (program costs, separate for clinic and WIC sites). Cost effectiveness can also be determined by combining the mean total cost per participant with change in primary outcomes. We will calculate the incremental cost-effectiveness ratio (ICER) for the CHW home intervention compared to usual care, such that $ICER_t = (C_1 – C_0) / (E_{1t} – E_{0t})$, where C is cost and E is effectiveness. Subscript 1 denotes CHW home intervention and subscript 0 denotes the comparison condition. t denotes the time period: 6 months and 12 months. 95% confidence intervals for the ICERs will be calculated to evaluate the uncertainty in these

results.[65-67] One-way and multi-way sensitivity analyses can be conducted for the key parameters to evaluate whether the ICERs are sensitive to plausible changes in their values. The sensitivity analysis is a check on the robustness and will determine the key parameters impacting the ICERs.

13 SOURCE DOCUMENTS AND ACCESS TO SOURCE DATA/DOCUMENTS

Study staff will maintain appropriate medical and 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. Study staff 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.

Source documents include paper and electronic data collection documents and digital images. Survey answers will be recorded either in REDCap or on paper case report forms (CRFs). Data will be documented either directly into REDCap or on paper CRFs. Images will be recorded digitally and then transferred to the UIC secure network servers after collection.

Three years after the end of the CO-OP Chicago research activity, data will be publicly released. Data sets will be stripped of all protected personal health information (PHI) to allow sharing of data without compromising participant confidentiality, privacy, and safety. All identification covered under HIPAA will have been removed. All remaining variables not covered under HIPAA will be evaluated in terms of the risk of deductive disclosure of identity, and appropriate measures will be taken to protect confidentiality. The stripped data will be maintained by the study team, in partnership with the community clinical partner. In order to ensure responsible usage of study data, user registration will be required to access or download data files. Registered users will receive technical assistance with questions or problems from the Methodology Research Core (MRC) at the University of Illinois at Chicago's Institute for Health Research and Policy or from the UCSF CC. A data sharing agreement will be required that will describe the conditions and restrictions of their use; limited data access will be made available only to users who successfully complete a rigorous approval process by both the investigators and the community partners. Data sets will be encrypted for transfer to approved investigators.

14 QUALITY CONTROL AND QUALITY ASSURANCE

Refer to the UCSF Coordinating Center (CC) Clinical Data Management Plan for additional details on data security and management. CO-OP Chicago will develop a Data Validation Plan in partnership with the CC Clinical Research Specialist and Data Manager specific to this project. The REDCap database is stored on the UCSF server. Access is given to UCSF and UIC staff on an as needed basis, as determined by the CC.

Data will be documented either directly into REDCap or on paper CRFs. Data collected on paper CRFs will be assessed for accuracy and completeness by research staff prior to data entry. Quality assurance checks will be implemented at the time data are entered into REDCap as an assurance of data accuracy for electronic data capture. Erroneous and/or inconsistent values will prompt generation of an entry to a query report that will be developed for this study. Query reports will be generated routinely and distributed to study staff for resolution. Once generated, a query will remain part of the report until it is resolved. The CC will generate standard and customized reports for data monitoring and quality assessment throughout the project. Additional reports can be generated if indicated.

Images will be recorded digitally and then transferred to the UIC secure network servers after collection. Images will be reviewed immediately after upload by RAs to ensure successful upload and saved using the participant ID number in the image name.

At the time the study database is constructed, the CC and CO-OP Chicago project manager will ensure that the electronic data capture system is in compliance with the approved NIDCR protocol and is in compliance with source documents. Ongoing adherence to the protocol and source documents is achieved by the reports described previously and by regular fidelity monitoring of RAs as described in Section 8.1. Source documents are described in Section 13. Quality assurance issues will be addressed at the site level and in partnership with the CC, depending on the issue. A more detailed plan will be developed with the CC before launching the trial.

UCSF CC is preparing a calibration protocol for calibration of assessment of plaque images. Other staff training methods are described in Section 8.1. Training of staff will be monitored by the CO-OP Chicago project manager.

15 ETHICS/PROTECTION OF HUMAN SUBJECTS

15.1 Ethical Standard

The investigator 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.

15.2 Institutional Review Board

The protocol, informed consent form(s), recruitment materials, and all subject materials will be submitted to the 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 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 participants and their families, if applicable. The RA will obtain written informed consent and parental permission from the caregiver before the start of the data collection. If the caregiver participant is not the legal guardian of the child but is the primary caregiver agreeing to participate, separate consent forms will completed by the caregiver participant and legal guardian. (An example of this is that sometimes grandmothers do the majority of the day-to-day care of a child but the mother is the legal guardian. In this instance, we would ask the mother to sign the parental permission informed consent for the child and the grandmother to sign the informed consent for herself.) A consent form describing in detail the study procedures and risks will be given to the participant. Consent forms will be IRB-approved, and the participant is required to read and review the document or have the document read to him or her. The RA will explain the research study to the participant and answer any questions that may arise. The participant will sign the informed consent document prior to conducting any study-related assessments or procedures. Participants 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 informed consent document will be given to participants for their records. The rights and welfare of the participants 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 clinical or research record.

All research staff, investigators, and clinical staff with access to data will undergo HIPAA and human subjects research training. Training is provided at the University of Illinois at Chicago through the Citi Program (*www.citiprogram.org*).

Consents for screening will be verbal, and written consent documents will be provided and signed when participants are enrolled in the trial. Note that assent is not used because all children will be under the age of 3 years old.

15.4 Exclusion of Women, Minorities, and Children (Special Populations)

This study conforms to NIH policies on the inclusion of women and minorities. Based on results from the CO-OP Chicago pilot phase and formative work, we anticipate 95% of caregivers will be female. The children will be approximately 50/50 male/female. We expect approximately 60% of families will be Hispanic ethnicity and approximately 40% will be African-American. This study includes children and conforms with NIH policy (Subpart D – Additional Protections for Children Involved as Subjects in Research, 45 CFR Part 46.401-46.409.)

15.5 Subject Confidentiality

Participant confidentiality is strictly held in trust by the investigators, study staff, and the sponsor(s) and their agents. This confidentiality applies to any study information relating to participants.

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 study documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) for the study participants. The clinical study site will permit access to such records.

All data and images will be kept confidential, and no subject will be identifiable from research records or published data. We will employ procedures used in other studies to maintain confidentiality of data. All case report forms (CRFs) will be coded with ID numbers only. Participant contact information will be stored separately from data files, and access to this information will be limited to the PI and research staff. The master list of ID code numbers and corresponding names will be kept in a locked file cabinet or in a password protected file on an internal server, with close scrutiny of access maintained by the PI. The master list is used only to coordinate data collection. Compliance with IRB and NIH regulations concerning data storage and destruction will be strictly observed. It is anticipated that research specialists, the database manager, and the project manager will have access to identifiable data.

15.6 Future Use of Stored Specimens and Other Identifiable Data

Not applicable.

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 participants, including accurate CRFs and other source documentation.

16.1 Data Management Responsibilities

Data collection and accurate documentation are the responsibility of the study staff under the supervision of the 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 investigator or designee.

16.2 Data Capture Methods

Data will be collected by research staff who will receive training on survey techniques and documenting data as well as tooth brushing technique and plaque index scoring. The data will be entered directly into REDCap or documented initially on CRFs and then entered into REDCap.

Images will be collected for quality assessments and data collection. Images will be recorded using a mobile recording device and then will be uploaded to the secure UIC server as soon as a Wi-Fi connection is established. The goal is to upload these immediate after the completion of the home visit. Images will then be deleted from the mobile recording device after the quality check has been completed.

CRFs will be transported to UIC and stored in locked file cabinets in a building that is accessible only with security identification.

16.3 Types of Data

The types of data include:

- Electronic data files on REDCap
- Images
- Paper CRFs
- Safety data (unanticipated problems)

16.4 Schedule and Content of Reports

Reports on recruitment and implementation for the study will be provided to the study team and NIDCR monthly. Data analysis and review will occur once data collection is complete.

16.5 Study Records Retention

Study records will be maintained for at least three years from the date that the grant final federal financial report (FFR) is submitted to the NIH.

16.6 Protocol Deviations

A protocol deviation is any noncompliance with the clinical study protocol or Good Clinical Practice requirements. The noncompliance may be on the part of the subject, the investigator, or study staff. As a result of deviations, corrective actions may to be developed by the study staff 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 reported to NIDCR and the local IRB, according to their requirements.

17 PUBLICATION/DATA SHARING 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.

Data from this study will be shared in accordance with the NIH Data Sharing Policy. *https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm*.

The National Institutes of Health (NIH) has issued a policy to promote broad and responsible dissemination of information from NIH-funded clinical trials through ClinicalTrials.gov. The policy establishes the expectation that all investigators conducting clinical trials funded in whole or in part by the NIH will ensure that these trials are registered at ClinicalTrials.gov, and that results information of these trials is submitted to ClinicalTrials.gov. Please see *https://www.federalregister.gov/documents/2016/09/21/22379/nih-policy-on-the-dissemination-of-nih-funded-clinical-trial.information*.

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SUPPLEMENTAL MATERIALS

APPENDICES

Appendix A: Schedule of Events

Appendix B: Survey Question Sources and Citations

Appendix C: Plaque Protocol

Appendix D: Contact Attempt and Window Protocol

Appendix E: CHW Action Plan

Appendix F: Caries Risk Assessment

Appendix G: Core Curriculum Delivery Guide

Appendix H: CHW Encounter Tracking Form

Appendix I: CHW Fidelity Assessment Form

Appendix J: Trial Consent Form English

APPENDIX A: SCHEDULE OF EVENTS

Schedule of Events

Procedures and Intervention		Screening (prior to baseline)	Enrollment/ Baseline Data Collection (prior to randomization)	Randomization (Day 0)	Intervention Visit 1 (Day 30, -23, +149)	Intervention Visit 2 (Day 90, -76, +89)	6-month Data Collection (Day 180, -14, +60)	Intervention Visit 3 (Day 240, -59, +124)	Intervention Visit 4 (Day 300, -199, +64)	Final Data Collection/ Study Completion (Day 365, -0, +90)	Premature Discontinuation*
Verbal Consent Form		X									
Signed Consent Form			X								
Assessment of Eligibility Criteria		X	X								
Self-report questionnaire: demographics, beliefs, behaviors, risk factors			X				X			X	
Review of Medical/Dental History			X				X			X	
Review of Concomitant Medications			X				X			X	
Plaque assessment (disclosing solution and image collection)			X				X			X	
Tooth brushing observation (home only)			X				X			X	
Physical Exam-ination	Number of teeth	X	X								
	Weight		X				X			X	
Study Intervention					X	X		X	X		
Assessment of Adverse Events			X				X			X	

*Premature discontinuation is not applicable. Participants that withdraw/are withdrawn will have no further data collection or intervention.

APPENDIX B: STUDY INSTRUMENTS AND SOURCES

Question number	Question	Type of Variable	Domain	Purpose	Source	Collection method
A2	Child frequency of brushing	Primary	Brushing behavior	Determine behavior	EC4/BRFQ	Self-report
A1	Child age started brushing	Secondary	Brushing behavior	Determine behavior	NHANES	Self-report
A5	Child age started using toothpaste	Secondary	Brushing behavior	Determine behavior	NHANES	Self-report
A3	Caregiver assistance with brushing	Secondary	Brushing behavior	Determine behavior	EC4/BRFQ	Self-report
A6-A7	Child type of toothpaste	Secondary	Brushing behavior	Determine behavior	CO-OP pilot	Self-report
A4	Child duration of brushing	Secondary	Brushing behavior	Determine behavior	CO-OP pilot	Self-report
A8	Child amount of toothpaste	Secondary	Brushing behavior	Determine behavior	NHANES	Self-report
A9a-o	Caregiver self-efficacy	Covariate	Self-efficacy	Predict/explain behavior	EC4/BRFQ	Self-report
A10-A15	Child oral health quality of life	Covariate	Quality of life	Assess if associated with child behaviors	ECOHIS	Self-report
A16a-j	Caregiver oral health quality of life	Covariate	Quality of life	Assess if associated with child behaviors	Oral Health Impact Profile	Self-report
A17	Caregiver sources of support for brushing	Covariate	Brushing risk factor	Identify caregiver supports	CO-OP pilot	Self-report
A18	Caregiver barriers to brushing	Covariate	Brushing risk factor	Identify barriers	CO-OP pilot	Self-report
A19	Child type of drinking water	Covariate	Oral health behavior	Identify sources of fluoride	EC4/BRFQ	Self-report
A20-A21	Child dental care utilization	Covariate	Oral health behavior	Determine rate, identify source of education and service receipt	NHANES	Self-report
A22	Last time child had teeth professionally cleaned	Covariate	Oral health behavior	Interpret plaque score	Modified from BRFSS	Self-report
A23-A24	Child barriers to dental care	Covariate	Oral health behavior	Identify barriers	NHANES	Self-report
A25-A26	Sugar sweetened beverages	Covariate	Oral health behavior	Identify risk factors	EC4/BRFQ	Self-report
A27-A28	Child type of cup/bottle	Covariate	Oral health behavior	Identify risk factors	EC4/BRFQ	Self-report
A29	Child cup/bottle at night	Covariate	Oral health behavior	Identify risk factors	EC4/BRFQ	Self-report

A30	Child caries history	Covariate	Oral health risk factor	Determine caries rate	CO-OP pilot	Self-report
A31	Child history of general anesthesia for dental	Covariate	Oral health risk factor	Assess risk for severe caries	CO-OP pilot	Self-report
A32	Sibling history of general anesthesia for dental	Covariate	Oral health risk factor	Assess risk for severe caries	CO-OP pilot	Self-report
A33a-e	Caregiver knowledge and attitudes on oral health	Covariate	Oral health beliefs	Assess if associated with child behaviors	EC4/BRFQ	Self-report
A34	Caregiver general oral health assessment	Covariate	Oral health risk factor	Assess if associated with child behaviors	NHIS	Self-report
A35	Caregiver brushing frequency	Covariate	Oral health risk factor	Assess if associated with child behaviors	EC4/BRFQ	Self-report
A36	Caregiver dental care utilization	Covariate	Oral health risk factor	Assess if associated with child behaviors	NHANES	Self-report
A37	Caregiver reason for last dental visit	Covariate	Oral health risk factor	Assess if associated with child behaviors	NHANES	Self-report
A38-A39	Caregiver barriers to dental care	Covariate	Oral health risk factor	Assess if associated with child behaviors	NHANES	Self-report
B1-B7	Child plaque: Oral Hygiene Index – Maxillary Incisor Simplified	Primary	Brushing behavior	Determine behavior	CO-OP and UCSF pilots	Observed
C1	Caregiver assistance with brushing	Secondary	Brushing behavior	Determine behavior	CO-OP pilot	Observed
C2	Type of toothpaste	Secondary	Brushing behavior	Determine behavior	CO-OP pilot	Observed
C3a-b	Duration of brushing, entire activity and actual brushing	Secondary	Brushing behavior	Determine behavior	CO-OP pilot	Observed
C4	Amount of toothpaste	Secondary	Brushing behavior	Determine behavior	CO-OP pilot	Observed
C5-C6	Mouth rinsed	Secondary	Brushing behavior	Determine behavior	CO-OP pilot	Observed
C7	Type of toothbrush	Secondary	Brushing behavior	Determine behavior	CO-OP pilot	Observed
C8a-l	Parenting during brushing	Covariate	Oral health risk factor	Assess if associated with child behaviors	Toothbrushing Observation System scale	Observed
D1-D26	Demographics	Covariate	Demographics	Describe participants	multiple	Self-report

D27	Weight	Covariate	Medical risk factor	Identify risk factors	CO-OP pilot	Measurement
D28a-e	Child medical history and medications	Covariate	Medical risk factor	Identify risk factors	Clinical practice	Self-report
D29	Caregiver general health	Covariate	Psychosocial risk factor	Identify risk factors	NHIS	Self-report
E1-E3	Caregiver psychological functioning	Covariate	Psychosocial risk factor	Identify risk factors	PROMIS anxiety, depression, functioning	Self-report
E4-E6	Caregiver social support	Covariate	Psychosocial risk factor	Identify risk factors	PROMIS Social Support Survey	Self-report
E7-12	Family functioning	Covariate	Psychosocial risk factor	Identify risk factors	CHAOS scale	Self-report
	CHW intervention delivery costs	Secondary	Cost	Assess cost effectiveness	Mileage logs, phone logs, expense reports	Mileage logs, phone logs, expense reports

CHAOS

The CHAOS scale was originally developed as a 15-item instrument that could be answered only as yes/no. (1) Matheny A, Wachs T, Ludwig J, Phillips K. Bringing order out of chaos: psychometric characteristics of Confusion, Hubbub and Order Scale. J Appl Dev Psychol. 1995;16:429-444. (2) Haach LM, Gerdes AC, Schneider BW, Hurtado GD. Advancing our knowledge of ADHD in Latino children: Psychometric and cultural properties of Spanish-versions of parental/family functioning measures. J Abnorm Child Psychol. 2011;39.1:33-43.

A subsequent study has used a modified 6-item version that allows a range of responses. (1) Coldwell J, Pike A, Dunn J. Household chaos--links with parenting and child behaviour. J Child Psychol Psychiatry. 2006 Nov;47(11):1116-22. (2) Deater-Deckard K, Mullineaux P, Beckman C, Petrill S, Schatschneider C, Thompson L. Conduct problems, IQ, and household chaos: a longitudinal multi-informant study. J Child Psychol Psychiatry. 2009;50(10):1301-1308. Both versions have been used in Chicago populations of caregivers; the 6-item scale is easier for families to understand and answer. Therefore that is what the study will use.

CO-OP Pilot

These questions were developed by the CO-OP Steering Committee with input from NIDCR Project Scientists and the Data Coordinating Center. All questions were tested in the pilot phase of the project.

Demographics

Gender, age, insurance, relationship, education level: Developed by CO-OP, tailored to our population and survey needs.
Employment: From EC4, original source Cancer Biomedical Informatics Grid (caBIG) 2003074(4).
Ethnicity: 2010 US Census. *https://www.census.gov/schools/pdf/2010form_info.pdf*
Time in the US, race, caregiver relationship status, people in the home: From previous Chicago studies in Hispanic, mixed-race populations. Martin MA, Mosnaim GS, Olson D, Swider S, Karavolos K, Rothschild S. Results from a community-based trial testing a community health worker asthma intervention in Puerto Rican youth in Chicago. J Asthma. 2015 Feb;52(1):59-70.

EC4/BRFQ

Items addressing oral health behavior were developed by the Knowledge and Behavior Workgroup of the EC4, which included faculty from each of the three Collaborating Centers: Judith Albino (UCD), Angela Brega (UCD), Kristin Hoeft (UCSF), Clemencia Vargas (BU), and Peggy Walsh (UCSF). Initial steps in item development involved identifying existing items. Items were then heavily adapted or newly developed to address the 12 key counseling messages expected to be communicated across all projects. The cross-center Behavioral Intervention Workgroup identified the key counseling messages, which then served to guide development of survey items related to knowledge and behavior. Members of the Behavioral Intervention Workgroup included the following: Belinda Borrelli (BU), Tracy Finlayson (UCSF), Karen Fehringer (UCD), Barbara Heckman (UCSF), Michelle Henshaw (BU), Carol Kaufman (UCD), Nancy Kressin (BU), Ruth Nowjack-Raymer (NIDCR), Melissa Riddle (NIDCR), Paul Spicer (UCD), and Peggy Walsh (UCSF).

***Citation*:** (1) Wilson A, Brega AG, Batliner TS, Henderson W, Campagna E, Fehringer K, Gallegos J, Daniels D, Albino J. Assessment of parental oral health knowledge and behaviors among American Indians of a Northern Plains tribe. *Journal of Public Health Dentistry*. J Public Health Dent. 2014 Spring;74(2):159-67. (2) Albino J, Tiwari T, Gansky SA, Henshaw MM, Barker JC, Brega AG, Gregorich SE, Heaton B, Batliner TS, Borrelli B, Geltman P, Kressin NR, Weintraub JA, Finlayson TL, Garcia RI, and the Early Childhood Caries Collaborating Centers. The basic research factors questionnaire for studying early childhood caries. *Manuscript under review.*

NHANES

For amount of toothpaste self-report, the caregiver will also be shown a picture demonstrating the response options; this modification originated from the NIDCR Project Scientists and the Data Coordinating Center.

Citation: Centers for Disease Control and Prevention (CDC). National Center for Health Statistics (NCHS). National Health and Nutrition Examination Survey Questionnaire (or Examination Protocol, or Laboratory Protocol). Hyattsville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, [2013-2014][www.cdc.gov/nchs/nhanes].

NHIS

Citation: Centers for Disease Control and Prevention (CDC). National Center for Health Statistics (NCHS). National Health Interview Survey (NHIS). Hyattsville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2008. [www.cdc.gov/nchs/nhis]

Oral Health Impact Scale

Citations: (1) Slade GD, Nuttall N, Sanders AE, Steele JG, Allen PF, Lahti S. Impacts of oral disorders in the United Kingdom and Australia. Br Dent J. 2005 Apr 23;198(8):489-93. (2) Slade GD. Derivation and validation of a short-form oral health impact profile. Community Dentistry & Oral Epidemiology 1997; 25:284-90. (3) Slade GD, Spencer AJ. Development and evaluation of the Oral Health Impact Profile. Community Dent Health,1994;11:3–11.

Oral Hygiene Index – Maxillary Incisor Simplified

This instrument was modified from the Simplified Oral Health Index (Greene JC, Vermillion JR. The simplified oral hygiene index. J Amer Dent Assoc 1964; 68: 7-13.) and pilot tested by CO-OP Chicago and UCSF during the pilot phase of the project.

ECOHIS

Citation: Pahel BT, Rozier RG, Slade GD. Parental perception of children's oral health: The Early Childhood Oral Health Impact Scale (ECOHIS). Health and Quality of Life Outcomes 2007;5:6-17.

PROMIS Instruments

Citations:

- Patient-Reported Outcomes Measurement Information System. Available at *http://www.nihpromis.org/measures/translations. Accessed 9/24/14*,
- Patient-Reported Outcomes Measurement Information System. Available at *http://www.assessmentcenter.net/documents/PROMIS%20Scoring%20Manual-%20CATs,%20Profiles,%20Short%20Forms.pdf.* Accessed 5/8/14.
- Pilkonis PA, Choi SW, Reise SP, Stover AM, Riley WT, Cella D; PROMIS Cooperative Group. Item banks for measuring emotional distress from the Patient-Reported Outcomes Measurement Information System (PROMIS®): depression, anxiety, and anger. Assessment. 2011 Sep;18(3):263-83.
- Hahn EA, Dewalt DA, Bode RK, Garcia SF, Devellis RF, Correia H, Cella D. New English and Spanish social health measures will facilitate evaluating health determinants. Health Psychology. 2014;epub ahead of print.

Toothbrushing Observation System

We used the parent items (12) from the Toothbrushing Observation System.

Citation: Collett BR, Huebner CE, Seminario AL, Wallace E, Gray KE, Speltz ML. Observed child and parent toothbrushing behaviors and child oral health. Int J Paediatr Dent. 2016 May;26(3):184-92.

APPENDIX C: PLAQUE PROTOCOL

CO-OP Chicago Plaque Protocol

This protocol was developed jointly between the CO-OP Chicago and UCSF investigators. The UCSF Coordinating Center is developing a calibration protocol for this measure for the Oral Health Disparities in Children Consortium (OHDC).

Background

Dental plaque is a biofilm that contains varying levels of cariogenic bacteria based on inherent microbiota and plaque age. The accumulation of dental plaque has been widely described in the literature as a significant risk factor for caries. Dental plaque on primary incisors is strongly predictive of future caries.[1] Most preventive behaviors emphasize removal of dental plaque to disrupt the cariogenic microbiota in the oral environment.

Many plaque scoring systems have been described in the literature, but none are specific to pediatric patients.[2] Plaque systems explored for this study include the Oral Hygiene Index, Silness-Löe Index, Simplified Oral Hygiene Index (OHI-S) and the Quigley-Hein Index with Turesky Modification.[3] Due to age, cooperation potential, and the eruption status of primary teeth, traditional scoring systems which include permanent teeth are not applicable to the 0 to 3-year-old population and require modifications before epidemiologic use.

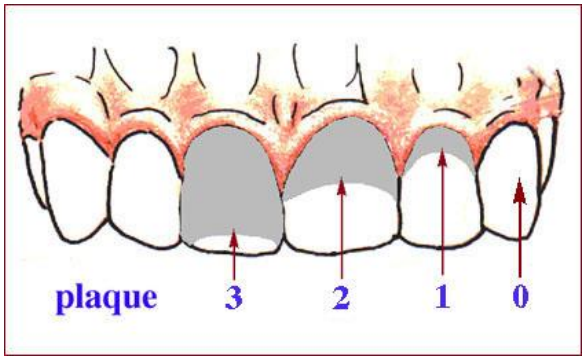
Simplified Oral Hygiene Index – Maxillary Incisor Scale (OHI-MIS)

The Simplified Oral Hygiene Index (OHI-S)[4] will be modified for use in young children with primary teeth, to assess the status of current oral hygiene, based on the amount of debris (plaque) present. The original Oral Hygiene Index (1960) scored 12 tooth surfaces with two components, a debris index and calculus index, to create a numerical determination of the overall oral hygiene. The Simplified index uses the same criteria to assign scores of 6 tooth surfaces (labial) instead of 12.[4]

Because this index is meant for adults, the OHDC modification of the OHI-S for young children scores 4 buccal (facial) tooth surfaces of the primary maxillary incisors, (d, e, f, and g also known as 52, 51, 61, 62 in the international tooth numbering system), denoted OHI-MIS. The OHI-MIS score will be determined after using plaque disclosing liquid which tints the plaque red making it visible. Then an extra-oral photographic image of the buccal (facial) surfaces will be taken to allow asynchronous scoring.

The criteria for classifying each surface for OHI-MIS will be the same as OHI-S.

Scores	Criteria
0	No debris or stain present
1	Soft debris covering not more than one-third of the tooth surface, or presence of extrinsic stains without other debris regardless of surface area covered
2	Soft debris covering more than one-third, but not more than two-thirds, of the exposed tooth surface
3	Soft debris covering more than two-thirds of the exposed tooth surface



At least two of the four possible surfaces must be examined for an individual score to be calculated. Partially erupted teeth should not be scored. **The OHI-MIS debris index = (buccal (facial) incisor scores d+e+f+g) / (Total number of examined surfaces)**. With this calculation, the score will range from 0 (best) to 3 (worst). To evaluate such systems for clinical relevance, Wei & Lang suggest "oral cleanliness is considered: 'good' if the score is between 0.3-0.6; 'fair' when it is 0.7-1.8; or 'poor' when the score is between 1.9-3.0."[4]

Procedures

Depending on the age and cooperation of the child, subjects will be reclined in a knee-to-knee position or seated upright. A research assistant will apply two drops of plaque disclosing solution to maxillary incisors with a disposable micro applicator brush with care not to disrupt the plaque biofilm. Plaque disclosing solution will be used per manufacturer's instructions. The specific product for use in this study is 2Tone (Young Dental). Instructions for use can be found on the following site: http://www.youngdental.com/product/2tone-disclosing-solution/# If needed, the child's mouth will be held open with a mouth prop.

The second research assistant will have a portable overhead light and a mobile phone camera (iPhone 7). After completing the disclosing steps and waiting approximately 15 seconds, the second research assistant will take a series of photographs of the teeth at a distance of approximately 18" above the subject. The second research assistant will verify appropriate capture of images. If images do not clearly capture all maxillary incisors with sufficient clarity and light, the images will be repeated.

References

1. Alaluusua S, Malmivirta R. Early plaque accumulation—a sign for caries risk in young children. *Community dentistry and oral epidemiology.* 1994; 22.5PT1: 273-276.
2. Wei SH, Lang NP. Periodontal epidemiological indices for children and adolescents: II. Evaluation of oral hygiene; III. Clinical applications. *Pediatric dentistry.* 1981;3(4):353-60.
3. Greene JC, Vermillion JR. The oral hygiene index: a method for classifying oral hygiene status. *Journal of the American Dental Association*. 1960; 61: 29-35.
4. Greene, JG, Vermillion JR. The simplified oral hygiene index. *Journal of the American Dental Association.* 1964; 68.1: 7-13.

APPENDIX D: CONTACT ATTEMPT AND WINDOW PROTOCOL

CO-OP Chicago

CONTACT ATTEMPT AND WINDOW PROTOCOL

Research Specialist: Data Collection

Windows

Type of Visit	Earliest start	Latest acceptable
Baseline	NA	NA
6-month	14 days before	60 days after
12-month	Date due	90 days after

Clock starts when randomized.
12-month due date does not change regardless of when 6-month data collection visit completed.

Attempts

- For main outcomes visit: 12-month
  - These are primary outcomes, need to try to get at all costs.
  - Contact every 2-4 days at varying times of day and varying types of mediums for first 2 weeks. Consider then reducing frequency of attempts but do not give up until window closed.
  - If phone not working, or no answer after 5 attempts, stop by home up to 2 times. If can talk with family, great. If not, then drop off letter.
  - If cannot drop off letter or no response to dropped off letter after 1 week, send certified letter.
  - If no response to anything, at minimum try to call once a week until window closed.
  - If ultimately family cannot do in person, do via telephone if feasible for family.
  - If phone not working/no answer, attempt to verify address and phone number at the subject's clinic/WIC.
  - If no answer from all phone numbers and letters, attempt to see if any scheduled appointments at subject's clinic/WIC. If yes, try to be at that appointment to talk with family before/after.
  - Track for each attempt
    - Date
    - Day of week
    - Time of day
    - Medium (phone call, text, email, letter, stopped at home) and number/address used
    - Comment section (note if family answered but can't talk now, family stood you up, talked with other family member and told to call back, etc)
- For 6-month
  - Same as 12-month but shorter window.

CHWs

Windows

4 visits over 12 months, preferred in person at home or other location face-to-face. Goal is 2 visits in first 6 months, 2 visits in second 6 months. Follow-up phone calls should be conducted after visits (total of 4).

- Additional contacts acceptable but not encouraged.
- CHW can call family to schedule as soon as randomization completed.
- Goal is one visit every 2-3 months
- No more than 2 in-person visits before the six month mark; no more than 2 in-person visits after the six month mark
- In-person visits cannot be closer than 30 days.

Attempts

- Contact every 2-4 days at varying times of day and varying types of mediums for first 2 weeks. Consider then reducing frequency of attempts to weekly for 4 weeks, then monthly.
- If phone not working, or no answer after 5 attempts, stop by home up to 2 times. If can talk with family, great. If not, then drop off letter.
- If phone not working/no answer, can verify address and phone number in subject's clinic/WIC.
- If no answer from all phone numbers and letters, look if any scheduled appointments at the clinic/WIC. If yes, try to be at that appointment to talk with family before/after.
- If no answer from all phone numbers and letters and has an identified provider, talk to providers and/or staff at the clinic/WIC to see if they know better way to contact the subject. Ask them to help in process.
- Send certified letter
- Track for each attempt
    - Date
    - Day of week
    - Time of day
    - Medium (phone call, text, email, letter, stopped at home) and number/address used
    - Comment section (note if family answered by can't talk now, family stood you up, talked with other family member and told to call back, etc)

APPENDIX E: CHW ACTION PLAN

COordinated Oral Health Promotion (CO-OP) Chicago

ACTION PLAN / PLAN DE ACCIÓN

Date:
Fecha:

In the next _____, we are going to: *what*
En las próximas _____, vamos a:

_____

_____

We will do this: *when*
Vamos a hacerlo: *cuando*

_____

_____

The following things may get in the way of our plan:
Es posible que las siguientes cosas puedan interferir en nuestro plan:

_____

_____

We will try to get past these barriers by:
Vamos a tratar de superar estos obstáculos**:**

_____

_____

Level of confidence/Nivel de seguridad:

1 2 3 4 5 6 7 8 9 10
Not very sure — Very sure
No estamos seguros — Estamos muy seguros

_____ _____
Signature of participant — Signature of CHW
Firma de participante — Firma de promotora/e

APPENDIX F: CARIES RISK ASSESSMENT

Caries Risk Assessment

American Academy of Pediatric Dentistry. Guideline on caries-risk assessment and management for infants, children, and adolescents. Pediatric Dentistry. 2013 Sep-Oct;35(5):E157-64.

Complete for each person present if family agrees.

Children ages 0-5 years old

Date:
CHW:
Child ID number (or initials and age if not index child):

	High Risk	Low Risk
Biological		
Mother/primary caregiver has active caries	Yes	
Family is low income	Yes	
Child has more than 3 between meal snacks or beverages that contain sugar per day	Yes	
Child is put to bed with a bottle containing natural or added sugar	Yes	
Child has special healthcare needs	Yes	
Child is a recent immigrant	Yes	
Protective		
Child receives fluoridated drinking water or fluoride supplements		Yes
Child has teeth brushed daily with fluoride toothpaste		Yes
Child receives topical fluoride from health professional		Yes
Child has dental home/regular dental care		Yes
Clinical Findings*		
Child has white spot lesions or enamel defects	Yes	
Child has visible cavities or fillings	Yes	
Child has plaque on teeth	Yes	

** CHWs should only do what they feel comfortable with and what family is comfortable with, can skip this section*

APPENDIX G: CORE CURRICULUM DELIVERY GUIDE

CO-OP CHICAGO CHW HOME VISIT Core Curriculum Delivery Guide

FIRST VISIT

Goals:
- *Get to know the family*
- *Find out what they want to get out of the project or work on first*
- *Make a plan for the next 3 visits*
- *Begin or complete one core curriculum module*

What to bring:
- *CHW Training Manual (with ppt slides)*
- *Caries Risk Assessment forms*
- *Action plans*
- *Laptop/tablet with hotspot*

1. Introduce yourself and tell a little about yourself.
2. Ask about them: general and then why they joined program
    a. What do they want to work on the most in the next year?
    b. What are the biggest oral health concerns they have?
3. Caries Risk Assessment for all family members participating
    a. Discuss scores
4. Get an idea about what they know, where they are at
    a. Oral health basics module
5. Make a plan for the next several visits about what content areas you will cover.
    a. Talk about what we have to offer
    b. Match what they are interested in with the content areas
    c. Outline plan for next 3 visits
6. Introduce action plans
    a. What they are, how they work, why we do them
    b. What does family want to change before next visit?
    c. Help family make action plan
    d. Give copy to participant
7. Plan for next visit
    a. Work with family to decide on a time for next visit

SUBSEQUENT HOME VISIT PROTOCOL

1. Greetings – 5 minutes
2. Review action plan – 10 minutes
    a. Discuss if action plan achieved. If yes, how. If no, why not and speculate on ways to achieve the plan in the future.
    b. Discuss belief in ability to change behaviors
3. Core Curriculum – 30 minutes
4. Action plan – 10 minutes
    a. What does family want to change?
    b. Help family make action plan
5. Plan for next visit – 5 minutes
    a. Work with family to decide on a time for next visit

TELEPHONE FOLLOW-UP VISITS

1. Greetings – 1 minute
2. Ask if any questions since last visit, discuss – up to 15 minutes
3. Review action plan, revise if needed – up to 10 minutes
4. Remind about next visit, confirm date, time, place – up to 5 minutes

Content Areas

Core Curriculum

1. Oral health basics
2. Tooth brushing
3. Fluoride
4. Weaning
5. Nutrition
6. Seeing the dentist

Materials list

- CHW Training Manual (with ppt slides)
- A Pediatric Guide to Children's Oral Health Flip Chart and Reference Guide
- NIDCR one-pager "A Healthy Mouth For Your Baby"
- Mouth with teeth Model
- Toothbrushes
- Floss
- Toothpaste
- Sippy cups
- Dental referral list
- Laptop/tablet with hotspot
- Business cards
- Project info and contact sheet
- Optional: food and drink containers

Depending on the content area, use the following pages as a guide.

Oral Health Basics

i. Goals:
1. *To define dental caries*
2. *To describe causes of caries.*
3. *To discuss importance of caries prevention.*

ii. What you need:
1. *CHW Training Manual (with ppt slides)*
2. *A Pediatric Guide to Children's Oral Health Flip Chart and Reference Guide*
3. *Mouth with teeth model*
4. *Handout: NIDCR one pager "A Healthy Mouth For Your Baby"*

A. Topic areas
   a. Present normal infant tooth development: "A Pediatric Guide to Children's Oral Health Flip Chart and Reference Guide" pages 2-3, mouth with teeth model
   b. If family interested, can present normal tooth anatomy: CHW Training ppt slide 10-11
   c. Ask caregiver to list causes of caries.
      i. Define caries: "A Pediatric Guide to Children's Oral Health Flip Chart and Reference Guide" page 5
   d. Ask caregiver to identify behaviors that could cause caries.
      i. Discuss all behaviors: "A Pediatric Guide to Children's Oral Health Flip Chart and Reference Guide" pages 6-9.
      ii. Make sure discuss
         1. Vertical transmission (caregiver to child from utensils, pacifiers, sharing food)
         2. Family history of caries
         3. Frequency foods/drinks without enough breaks
         4. Sleeping with a bottle or cup
         5. Sugary foods/drinks
         6. Gummy foods
         7. Some medical conditions (that impair child's saliva, ability to participate in brushing, or require special medicines)
      iii. If family interested, can discuss bacteria and how bacteria interact with sugar to form caries
   e. Describe different stages of tooth decay (i.e. white spots, brown spots)
      i. Show pictures: "A Pediatric Guide to Children's Oral Health Flip Chart and Reference Guide" page 6, CHW Training ppt slide 12, 19, 24-26
   f. Discuss importance of caries prevention, emphasize they can prevent caries from happening and stop those that have already started (CHW will explain how)
      i. Give handout "A Healthy Mouth For Your Baby"

2. Brushing Basics

i. *Goals:*
   1. Describe when to start brushing teeth (or wiping gum line)
   2. *Describe how and when to brush teeth*
   3. *Describe types of toothbrushes*
   4. *Describe types and amount of toothpaste*
   5. *Explain how to floss*

ii. *What you need:*
   1. *CHW Training Manual (with ppt slides)*
   2. *Mouth with teeth model and toothbrush*
   3. *Toothpaste (for demonstration of quantity)*
   4. *Laptop/tablet with hotspot*

A. Topic areas
   a. Discuss when caregiver should start wiping gum line or brushing child's teeth
   b. Discuss how often to brush
      i. If needed, discuss strategies to remember
   c. Show caregiver on model teeth how to brush
      i. Discuss brushing technique
      ii. Discuss brushing duration
      iii. If needed, discuss strategies to help (timers, songs, etc)
   d. Show caregiver photo on how much toothpaste to use (CHW Training Manual ppt slide 45). Could also show on real toothbrushes.
   e. Show video on tooth brushing based on child's age (i.e. baby vs toddler)
      i. Baby:
         1. *https://www.youtube.com/watch?v=kyJo7vUpbT8*
         2. *https://www.youtube.com/watch?v=KB8mwBfcrXw*
      ii. Child:
      http://www.colgate.com/en/us/oc/oral-health/basics/brushing-and-flossing/video/No-More-Nasties-Brushing-for-Kids
      iii. Adult:
      https://www.youtube.com/watch?v=ImmFRJjadOI&index=3&list=PLEbUg8bEgmRWGhvM1KgvX9bA_FkbG9WEM
   f. Discuss different types of toothbrushes
   g. Discuss roll of spitting
   h. Show caregiver how to floss teeth and when to start
   i. Talk about how to store toothbrushes
   j. Practice brushing (and flossing if family wants)

3. Fluoride

i. Goals:

1. *To know what fluoride is and how it prevents cavities*
2. *Understand fluoride recommendations for toothpaste*
3. *To know benefits of fluoridated water (tap water) as opposed to bottle water*
4. *To know why fluoride varnish is applied*
5. *Dispel fluoride myths*

ii. What to bring:

1. *CHW Training Manual (with ppt slides)*
2. *Different kinds of toothpaste (infant, child, adult regular, no fluoride adult)*

A. Topic areas
   a. Ask if caregiver knows what fluoride is
      i. Discuss what it is and why it is important.
         1. Makes teeth stronger to resist caries
         2. Can rebuild teeth when some damage
         3. Has some anti-bacterial properties
   b. Identify day-to-day activities that provide teeth with fluoride
      i. Toothpaste
         1. Ask what kind of toothpaste they use for themselves and children, and why
         2. Explain recommendation for fluoride toothpaste
         3. Practice reading labels to identify fluoride
      ii. Water
         1. Ask if they know about fluoride in water
         2. Discuss types of water they drink (bottled, filtered, tap)
            a. Explain amount of fluoride in those
            b. If no fluoride in source of water, explain how to fix that (change type of water or add fluoride)
   c. Ask if families have received fluoride varnish
      i. Show picture (CHW Training manual ppt slide 40) or show demo varnish kit
      ii. Discuss where and when to get (i.e. dentist and/or pediatric office)
   d. Discuss concerns for too much fluoride, provide reassurance

4. Weaning

i. Goals:

1. *To identify age when child should transition from bottle to cup*
2. *To identify sippy cup recommendations*
3. *To discuss effects of nighttime feeding*

ii. What to bring:

1. *CHW Training Manual (with ppt slides)*
2. *A Pediatric Guide to Children's Oral Health Flip Chart and Reference Guide*
3. *Consider bringing different kinds of sippy cups (hard top, soft tops)*

A. Topic areas
   a. Ask about sleeping with the bottle or cup
      i. Discuss recommendations: never allow sleeping with bottle/cup
      ii. Remind families consequences, review baby bottle caries if needed
      iii. Discuss challenges encountered and strategies
   b. Ask caregiver to state the age in which a child should transition to a cup
      i. Discuss recommendations: Change over to sippy cup/regular cup at 1
      ii. Remind families consequences, review baby bottle caries if needed
      iii. Discuss challenges encountered and strategies
   c. Discuss types of sippy cups
      i. Explain why hard top cups preferred

5. Nutrition

i. Goals:

1. *To identify foods that contribute to caries*
2. *To identify beverages, including juice, that affect oral health*
3. *To identify effects of frequent snacking*
4. *To identify healthy foods*

ii. What to bring:

1. *Consider bringing some juice containers, fruit snacks, gummy vitamins, soda containers to read labels and compare*

A. Topic areas

a. Ask caregiver what food or beverage items can cause caries. In discussion:
   i. Emphasize sugar-sweetened beverages (avoid)
      1. Sodas also have acid which hurts teeth
   ii. Discuss juice (sugar in natural pure juice is still sugar, don't recommend)
   iii. Gummies, fruit snacks, and sticky foods (avoid)
   iv. Candy (avoid)
   v. Discuss milk and breastfeeding (sugar in milk too, need to clean teeth afterwards)

b. Discuss caregiver about frequent snacking and how it contributes to caries
   i. Frequent foods but more likely frequent drinking (includes milk/breastmilk)
   ii. Emphasize breaks in feeding

c. Discuss strategies for limiting sugar-sweetened beverages, unhealthy snacks, and frequency
   i. Kids want to do what their parents do…
   ii. Engage family in discussion,

d. Inform caregiver what food items are healthy for child
   i. Foods that clean the teeth while eating them
      1. Fresh fruits and vegetables
      2. Crunchy foods (apples, pears, carrots, salads, etc)
   ii. Variety

6. Seeing the Dentist

i. Goals:
1. *To know when a child should see a dentist*
2. *What to expect at first dental visit*
3. *How often should child go to dentist*
4. *To know the responsibility of a medical provider in oral health*

ii. What to bring:
1. *Dental referral list*

A. Topic areas
- a. Discuss when a child should start going to the dentist and why
  - i. At 1 year of age or within 6 months of getting first tooth
  - ii. Why: Start fluoride, receive education, identify any problems, get child used to the dentist
- b. Identify/list what will happen at first dental visit
  - i. Teeth examined
  - ii. Fluoride applied
- c. Discuss how often child should go to dentist
  - i. Every 6 months
- d. Discuss challenges to bring child to dentist, and problem solve
  - i. Insurance (Medicaid covers dental for children but not all dentist accept it)
  - ii. Finding dentist that will take babies
    1. Dental referral list
  - iii. Scheduling
  - iv. Transportation
  - v. Child resistance or fear
  - vi. Children with special needs
- e. Discuss the role a pediatrician or family doctor has regarding oral health
  - i. Should be screening and can often apply varnish
- f. Ask caregiver if he/she receives dental care and if he/she would like assistance
  - i. Dental referral list
  - ii. Insurance assistance

APPENDIX H: CHW ENCOUNTER TRACKING FORM

Participant ID _____

CHW _____

ENCOUNTER DOCUMENTATION

Participant Name_____ **Time Encounter Began** _____

Accompanied by: ₁☐ no one ₂☐ someone (name: _____) **Time Encounter Ended** _____

Encounter Number (circle one): 1 2 3 4 Follow-up call 1 Follow-up call 2 Follow-up call 3 Follow-up call 4 other_____

Encounter Location: ₁☐ clinic (specify_____) ₂☐ WIC (specify_____) ₃☐ home ₄☐ other (specify_____)

Date of Encounter: _____

CARIES RISK ASSESSMENT

☐ Completed ☐ Not completed because already done at past visit ☐ Not completed for other reason (describe):_____

CORE CURRICULUM

TOPIC	*Check one*	SUBTOPICS	MATERIALS USED	Details and Comments
1. Oral health basics	☐ Major topic of visit→ ☐ Minor topic of visit→ ☐ Not covered	☐ Normal tooth development ☐ Tooth anatomy ☐ What are caries ☐ Causes of caries ☐ Importance of caries prevention ☐ Other (specify):	☐ CHW Training Manual ☐ A Pediatric Guide to Children's Oral Health Flip Chart and Reference Guide ☐ Mouth with teeth model ☐ A Healthy Mouth For Your Baby handout ☐ Other (specify):	
2. Tooth brushing	☐ Major topic of visit→ ☐ Minor topic of visit→ ☐ Not covered	☐ When to start ☐ Frequency ☐ Technique ☐ Duration ☐ Equipment ☐ Toothpaste amount ☐ Spitting ☐ Flossing ☐ Other (specify):	☐ CHW Training Manual ☐ Mouth with teeth model ☐ Toothbrushes given ☐ Floss given ☐ Tooth brushing videos ☐ Other (specify):	
3. Fluoride	☐ Major topic of visit→ ☐ Minor topic of visit→ ☐ Not covered	☐ Define fluoride and roles ☐ Toothpaste ☐ Water	☐ CHW Training Manual ☐ Toothpaste ☐ Other (specify):	

		☐ Varnish ☐ Fluoride risks/myths ☐ Other (specify):		
4. Weaning	☐ Major topic of visit→ ☐ Minor topic of visit→ ☐ Not covered	☐ When to transition from bottle ☐ Sippy cup recommendations ☐ Nighttime feeding ☐ Other (specify):	☐ CHW Training Manual ☐ Sippy cups ☐ Other (specify):	
5. Nutrition	☐ Major topic of visit→ ☐ Minor topic of visit→ ☐ Not covered	☐ Sugar-sweetened beverages ☐ Juice ☐ Sticky foods, candy, etc ☐ Frequency of foods/drinks ☐ Healthy foods ☐ Other (specify):	☐ Other (specify):	
6. Seeing the dentist	☐ Major topic of visit→ ☐ Minor topic of visit→ ☐ Not covered	☐ When to start ☐ What to expect ☐ Frequency ☐ Role of the pediatrician ☐ Other (specify):	☐ Dental referral list ☐ Other (specify):	
7. Other topics	☐ Major topic of visit→ ☐ Minor topic of visit→	Describe:		

☐ Not covered			

ACTION PLAN

Did family accomplish their Action Plan from the last visit?

☐ Yes (exactly as they had planned)

☐ No, not even close. Why?

_____

☐ Some but not all. Why?

_____

ENCOUNTER PARTICIPATION

Did the target child participate? 1☐ Yes 2☐ No **If yes, how much did they participate?** 1☐ A lot 2☐ A little 3☐ Not at all

List each other person who participate in the visit and the amount they participated:

Person 1: First name: _____ Relationship to child: _____ Participated: 1☐ A lot 2☐ A little 3☐ Not at all

Person 2: First name: _____ Relationship to child: _____ Participated: 1☐ A lot 2☐ A little 3☐ Not at all **Person 3:** First name: _____ Relationship to child: _____ Participated: 1☐ A lot 2☐ A little 3☐ Not at all **Person 4:** First name: _____ Relationship to child: _____ Participated: 1☐ A lot 2☐ A little 3☐ Not at all **Person 5:** First name: _____ Relationship to child: _____ Participated: 1☐ A lot 2☐ A little 3☐ Not at all **Person 6:** First name: _____ Relationship to child:

_____ Participated: 1☐ A lot 2☐ A little 3☐ Not at all **Person 7:** First name:

_____ Relationship to child: _____ Participated: 1☐ A lot 2☐ A little 3☐ Not at all **Person 8:** First name: _____ Relationship to child: _____ Participated: 1☐ A lot 2☐ A little 3☐ Not at all

SELF EVALUATION

Self-Evaluation – How did I (the CHW) do today?					**How much progress do I feel was made on this visit?**			
1	2	3	4	5	1	2	3	4
Poor	Mediocre	Satisfactory	Good	Excellent	None	Some	Good	Great

List anything else that happened or seems important here:

APPENDIX I: CHW FIDELITY ASSESSMENT FORM

CHW Fidelity Assessment Form

Date:

Time:

CHW:

Supervisor:

Directions: For items, 1-9, assess the CHW on a scale from 1 – 5. Calculate the average rating at the bottom of the page.

1 Needs review of content and additional practice in this area
2 Demonstrates a basic understanding of the skill and is ready to practice a more complicated skill
3 Demonstrates an adequate understanding of a complicated skill, but needs more practice before starting on a clinical trial
4 Demonstrates an adequate understanding of the skill and is ready for entering the field on a clinical trial
5 Demonstrates a sophisticated understanding of the skill and could likely be role model for his/her peers.
N/E Not evaluated: This role play scenario did not allow opportunity to evaluate this skill

	SKILL	RATING	COMMENTS/SUGGESTIONS
1	ACCURACY OF CONTENT: CHW demonstrates knowledge of oral health information or self-management skill.		
2	CLARITY OF CONTENT: Communicates content in lay person's language, keeps the level of detail simple, and limits amount of material covered so it's likely to be retained, and not overwhelm the participant.		
3	OPENNESS TO QUESTIONS: Responds to questions from participant. If CHW does not know the answer, talks about how participant could pursue the answer or assures participant that they will learn what they can and get back to them at the next meeting.		
4	INDIVIDUALIZING the CONTENT and PROCESS: Shows an ability to find out what is most relevant to this participant and tailors the protocol to maximize acceptance of material.		
5	MODEL & GUIDE: CHW used modeling and experiential learning. Used conversational and problem-solving approaches (rather than lecture or debate) to promote guided discovery and learning, helping participants to draw their own conclusions.		
6	CHECK FOR PARTICIPANT UNDERSTANDING of MATERIAL: CHW checks for participant understanding by asking the participant to answer open-		

	ended questions, to put presented material into their own words, and/ or to demonstrate knowledge by practicing the skill within the session.		
7	ACTION: Discussed an action plan for weekly practice of skills. Encouraged participant to tie the content of material to their daily lives by developing a plan to take some action or to practice a skill in the time before their next meeting.		
8	ASKED FOR FEEDBACK: CHW asked participant for feedback on how this meeting and the overall process in the study is going.		
9	INTERPERSONAL EFFECTIVENESS: CHW displayed optimal levels of warmth, concern, confidence, genuineness, professionalism, and maintained appropriate boundaries.		
	AVERAGE RATING (Calculated)		

Average score of <4 requires evaluation and possible remediation.

APPENDIX J: TRIAL CONSENT FORM ENGLISH

University of Illinois at Chicago Consent for Participation in Research
Protocol Title: *COordinated Oral health Promotion (CO-OP) Chicago – Pilot Study*

Principal Investigator: Molly Martin, MD
Phone Number: 312-996-2363
Email: mollyma@uic.edu

Leave box empty - For office use only

You are being asked to participate in a research study. Researchers are required to provide a consent form such as this one to tell you about the research, to explain that taking part is voluntary, to describe the risks and benefits of participation, and to help you to make an informed decision. You should feel free to ask the researchers any questions you may have.

Principal Investigator Name and Title: Dr. Molly Martin
Department and Institution: University of Illinois at Chicago Department of Pediatrics
Address and Contact Information: 1747 West Roosevelt Road, Room 547, M/C 275, Chicago, IL 60608
Sponsor: National Institute of Dental and Craniofacial Research at the National Institutes of Health

Why am I being asked?
You are being asked to be a subject in a research study that is trying to better understand dental cavities in children. You have been asked to participate in the research because you are a parent or guardian of a child who is at risk for dental cavities. Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future dealings with the University of Illinois at Chicago, with your clinic, and with your Women, Infant, and Children (WIC) center. **If you decide to participate, you are free to withdraw at any time without affecting these relationships.**

Approximately 420 subjects may be involved in this research at UIC.

What is the purpose of this research?
The purpose of this study is to better understand how to help parents take care of their children's teeth and prevent cavities.

What procedures are involved?
If you and your child participate in the study, you agree to participate for about one year. During the year, you and/or your child will be expected to participate in up to 7 in-person

visits that will last about one hour each, and 4 follow-up telephone calls or text messages that each require a few minutes of your time. Some people will be in a group that requires all 7 visits, and some people will be in a group that has only 4 study visits.

The first thing that happens is we collect information from you. To do this, we ask that you allow two University of Illinois research specialists to go to your home, or a location of your choice, and ask you some questions about you, your family, and about dental care in your family. During this visit, we will ask you to:

1) Answer questions about your family's beliefs about how to take care of teeth and what you do to take care of your family's teeth;
2) Answer questions about your health and your child's health;
3) Allow us to put a gel on your child's teeth that shows us where plaque is. Then we will look at your child's teeth and take pictures of the teeth; A dental professional will look at the pictures for your child's teeth to understand how much plaque is on your child's teeth.
4) Allow us to look at the space where your child's teeth are brushed;
5) Demonstrate for us how your child's teeth are brushed.

This visit will take about one hour. We will contact you 6 months later to repeat these questions. We will contact you one year after you started the program to repeat these questions one last time.

After enough people from your clinic or WIC center have signed up for the study, your clinic or WIC center will be randomly assigned either to have a community health worker (CHW) available for patients or clients or to continue with usual care. Randomization is like the flip of a coin. This means about half of clinics and WIC centers will have CHW services and half will not. If you are a patient or client at one of the clinics or WIC centers that gets a CHW, then you will be offered CHW services during the study. If you are a patient or client at one of the clinics or WIC centers that does not get a CHW, you will be offered one CHW visit at the end of the study after the final data collection.

If you are in a clinic or WIC that has CHW services, you will receive a letter with your CHW's information in it a few weeks after your data are collected. The CHW will meet with you four times over one year, about every three months. These visits can be in your home, the clinic, the WIC, or wherever you choose. During these visits, the CHW will talk with you and your family about how to care for your family's teeth. CHW visits will last about one hour each. After each visit, the CHW will call or text you to see how you are and ask if you have questions.

If you are in a clinic or WIC that does not have CHW services, you will be contacted by a CHW several weeks after your one year data collection visit. The CHW will offer to meet with you and your family at a location of your choosing for 1-2 hours for education and support.

We will let your clinic or WIC center know that you are enrolled in this study.

How long will I be in the study?
You will be in this study for approximately one year.

What are the potential risks and discomforts?
A risk of this research is loss of privacy (revealing to others that you are taking part in this study) or confidentiality (revealing information about you to others whom you have not given permission to see this information). It is possible that you or your child may feel uncomfortable and experience distress during the time we are asking you to answer questions and demonstrate tooth brushing behaviors, or while we are examining your child's teeth for plaque. If the study activities seem unacceptable to you or your family, you are free to not participate in the study. If information is revealed about child abuse or neglect, the law requires that this information be reported to the proper authorities.

Are there benefits to taking part in the research?
You will not directly benefit from participation in the research. The study results will be used to design future programs to help children and their families.

What other options are there?
You have the option to not participate in this study.

What about privacy and confidentiality?
The people who will know that you are a research subject are members of the research team, CHWs, and your clinic or WIC center. No information about you, or provided by you, during the research, will be disclosed to others without your written permission, except if necessary to protect your rights or welfare or if required by law.

Study information which identifies you and the consent form signed by you may be looked at and/or copied for examining the research by the National Institutes of Health, the UIC Office for the Protection of Research Subjects, the University of California San Francisco, or the State of Illinois Auditors.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

Confidentiality will be maintained by keeping research records in locked file drawers within a locked office. Each participant will be given an identification number to ensure confidentiality of the data files. The information linking participants' names and identification number will be kept in a locked room in locked file cabinets. Once collected, your data will not be available to anyone other than the investigators involved in this project. Data that identifies you will be destroyed one year after the completion of the study.

How will your health information be protected?
The researchers agree to protect your health information and will only share this information as described within this research consent form.

What are the costs for participating in this research?
There are no costs to you for participating in this research.

Will I be reimbursed for any of my expenses or paid for my participation in this research?
You will receive $40 in cash upon completion of each data collection. There are three data collections, so at the end of the study you may have received a total of $120.

Can I withdraw or be removed from the study?
If you decide to participate, you are free to withdraw your consent and discontinue participation at any time. All you need to do is contact the principal investigator at the phone number on this form. The researchers also have the right to stop your participation in this study without your consent if they believe it is in your best interests.

Who should I contact if I have questions?
Contact Dr. Molly Martin (principal investigator) at 312-996-2363, email *mollyma@uic.edu*.

- if you have any questions about this study or your part in it,
- if you have questions, concerns or complaints about the research.

What are my rights as a research subject?
If you feel you have not been treated according to the descriptions in this form, or if you have any questions about your rights as a research subject, including questions, concerns, complaints, or to offer input, you may call the Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at *uicirb@uic.edu*.

REMEMBER

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University of Illinois at Chicago, with your clinic, and with your WIC center. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

Signature of Participant

You have read (or someone has read to you) the above information. You have discussed the procedures, risks and benefits of the study with the researchers. You have been given an opportunity to ask questions and your questions have been answered to your satisfaction. You agree to participate in this research. You will be given a copy of this signed form for your information and to keep for your records. The original copy will be stored in the research file at the University of Illinois at Chicago.

Please check one

□ Yes, you can contact me about future research studies _____ (Initials of Participant)

□ No, do not contact me about future research studies

_____ _____

Signature Date

_____

Printed Name

I have discussed the above research study, including the purpose, risks, and benefits, with the subject. I encouraged questions and answered all questions that were asked. The subject is aware that he/she does not have to participate in the research and may later withdraw their consent.

_____ _____ _____

Signature of Person obtaining consent Date *(Same as Subject's)* Printed Name