Community-Based Intergenerational Oral Health Study

Protecting Your Child’s Teeth Begins In Pregnancy

NIDCR Protocol Number: 09-016E

NIDCR Funding Mechanism: RFA-DE-08-008 Centers to Reduce Disparities in Oral Health

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NIDCR Medical Monitor: Holli Hamilton

Version Number: Version 4.0

Day Month Year 3/11/2010
STATEMENT OF COMPLIANCE

The study will be carried out in accordance with Good Clinical Practice (GCP) as required by the following:

- ICH E6; 62 Federal Register 25691 (1997)
- NIH Clinical Terms of Award

All key personnel (all individuals responsible for the design and conduct of this study) will 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.

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Title
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<td>AAPD</td>
<td>American Academy of Pediatric Dentistry</td>
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<td>AAP</td>
<td>American Academy of Pediatrics</td>
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<tr>
<td>AE</td>
<td>Adverse Event/Adverse Experience</td>
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<td>BMI</td>
<td>Brief Motivational Interviewing</td>
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<td>CAMBRA</td>
<td>Caries Management by Risk Assessment</td>
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<td>CDT</td>
<td>Current Dental Terminology</td>
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<td>CES-D</td>
<td>Center for Epidemiologic Studies Depression Scale</td>
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<tr>
<td>CFR</td>
<td>Code of Federal Regulations</td>
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<td>CRF</td>
<td>Case Report Form</td>
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<tr>
<td>CPI</td>
<td>Co-Principal Investigators</td>
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<td>CSOC</td>
<td>Clinical Study Oversight Committee</td>
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<tr>
<td>DHHS</td>
<td>Department of Health and Human Services</td>
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<td>DMAP</td>
<td>Oregon Division of Medical Assistance Programs</td>
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<td>ECOHIS</td>
<td>Early Childhood Oral Health Impact Scale</td>
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<td>FWA</td>
<td>Federal Wide Assurance</td>
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<td>GCP</td>
<td>Good Clinical Practice</td>
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<tr>
<td>HIPAA</td>
<td>Health Insurance Portability and Accountability Act</td>
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<tr>
<td>ICF</td>
<td>Informed Consent Form</td>
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<tr>
<td>ICH</td>
<td>International Committee on Harmonisation</td>
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<td>ICMJE</td>
<td>International Committee of Medical Journal Editors</td>
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<td>IRB</td>
<td>Institutional Review Board</td>
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<td>ISM</td>
<td>Independent Safety Monitor</td>
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<td>KBU</td>
<td>Knowledge of Bottle Use Scale</td>
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<td>KCOH</td>
<td>Knowledge of Children’s Oral Health Scale</td>
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<td>M-DAS</td>
<td>Modified Dental Anxiety Scale</td>
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<tr>
<td>MI</td>
<td>Motivational Interviewing</td>
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<td>MOP</td>
<td>Manual of Procedures</td>
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<tr>
<td>N</td>
<td>Number (typically refers to subjects)</td>
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<td>NCROHD</td>
<td>Northwest Center to Reduce Oral Health Disparities</td>
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<td>NIDCR</td>
<td>National Institute of Dental and Craniofacial Research, NIH, DHHS</td>
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<td>NIH</td>
<td>National Institute of Health</td>
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<td>NMCOHRC</td>
<td>National Maternal Child Oral Health Resource Center</td>
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<td>OCTOM</td>
<td>Office of Clinical Operations and Management, NIDCR, NIH, DHHS</td>
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<tr>
<td>OHF</td>
<td>Oral Health-Related Fatalism Scale</td>
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<td>OHIP</td>
<td>Oral Health Impact Profile</td>
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<td>OHP</td>
<td>Oregon Health Plan</td>
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<td>OHRP</td>
<td>Office of Human Research Protections</td>
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<td>OHSE</td>
<td>Oral Health Self-Efficacy Scale</td>
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<td>PHI</td>
<td>Protected Health Information</td>
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<td>PI</td>
<td>Principal Investigator</td>
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<tr>
<td>Abbreviation</td>
<td>Description</td>
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<td>PMC</td>
<td>Pubmed Central</td>
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<td>PRL</td>
<td>Pregnancy Readiness Ladder</td>
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<td>PSS</td>
<td>Perceived Stress Scale</td>
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<tr>
<td>QA</td>
<td>Quality Assurance</td>
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<td>QC</td>
<td>Quality Control</td>
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<td>RPAC</td>
<td>Research Program Administrative Center</td>
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<td>SAE</td>
<td>Serious Adverse Event/Serious Adverse Experience</td>
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<td>S&amp;DCC</td>
<td>Statistical and Data Coordinating Center</td>
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<td>SMC</td>
<td>Safety Monitoring Committee</td>
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<td>SOP</td>
<td>Standard Operating Procedure</td>
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<td>WIC</td>
<td>Supplemental Nutrition Program for Women, Infants, and Children</td>
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PROTOCOL SUMMARY

Title: Community-Based Intergenerational Oral Health Study (aka Baby Smiles – Protecting Your Child’s Teeth Begins In Pregnancy)

Précis: This is a randomized trial using a brief motivational intervention given during the prenatal and/or postnatal period(s) to increase utilization of dental care and improve the oral health of rural, low-income pregnant and postpartum women (N=400) and their children, and to increase the number of oral health practices taken by these women to prevent caries in their young children. The intervention will be a two-part brief motivational interviewing (Brief MI) intervention provided to low-income women in four rural Oregon counties. The first part will be focused on pregnant women; the second part will be focused on their live born children. Women in each county will be randomized to one of four groups: Prenatal MI/Postpartum MI, Prenatal MI/Postpartum Traditional Health Education, Prenatal Traditional Health Education/Postpartum MI, and Prenatal Traditional Health Education/Postpartum Traditional Health Education.

Objectives: The aim is to test a community-based intervention trial using brief motivational interviewing provided to low-income women during the prenatal and/or postpartum period(s) to; (1) increase utilization of dental care during pregnancy or the postpartum period, and (2) increase utilization of preventive dental care by their young children.

Population: 400 pregnant women located in four counties within Oregon State

Phase: Phase 3

Number of Sites: 4

Study Duration: 5 years

Subject Participation Duration: Approximately 24 months (6 months during pregnancy; 18 months after birth)

Description of Agent or Intervention: The intervention will be a two-part Brief Motivational Interviewing (MI) intervention provided to low-income women in rural Oregon counties. The first part will be focused on pregnant women (prenatal period); the second part will be focused on their liveborn children (postpartum period). There will be four groups:
<table>
<thead>
<tr>
<th>Pregnancy (Prenatal) MI</th>
<th>Child (Postpartum) MI</th>
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<tbody>
<tr>
<td>Yes</td>
<td>Yes</td>
</tr>
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<td></td>
<td>No</td>
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Traditional Health Education: The control group in our study will receive a modified Traditional Health Education: The prenatal education materials are written materials published by the National Maternal Child Oral Health Resource Center (NMCOHRC; “Two Healthy Smiles”) supplemented with a brief video (~10-15 minutes) that covers the information in the written pamphlet. Women will also receive information about using their dental care coverage, guidelines to being a successful dental patient, and a “prescription” for good oral health care. The postpartum materials are written materials published by the National Maternal Child Oral Health Resource Center (NMCOHRC; “Two Healthy Smiles”, “A Healthy Smile For Your Baby”, and “A Healthy Smile For Your Young Child) and also from NMCOHRC (“Topical fluoride recommendations for high risk children”). A supplemental video will also be provided (~10-15 minutes) on preventing early childhood dental decay. We will also include the “prescription” for good oral health care again.

Brief Motivational Interviewing (BMI) Intervention: The MI intervention will involve brief counseling and follow-up with the use of materials that motivate and provide choices among community-recommended strategies to utilize preventive dental services and engage in home care activities to prevent tooth decay provided by local trained women in a Women, Infants, and Children (WIC) or public health (PH) setting. Participants will also receive the traditional health education materials as described above for each stage.
The prenatal MI participants will receive one-to-one in-person counseling during pregnancy (after enrollment). The counselor will identify their dental needs, their dental risks, reinforce their dental needs, and navigate barriers to care. During the first MI visit, the counselor will utilize both a written and electronic protocol (~30 minutes) to deliver the intervention. Within six weeks of the in-person sessions, the counselor will provide two follow-up telephone sessions. Additionally, participants will receive a phone call 1 month prior to birth. Its purpose is to inquire about their pregnancy as well as dental issues.

The postpartum MI participants will receive their first child-centered MI session at 9 months post-partum. The content will focus on the child and include preventive strategies such as oral hygiene and dietary practices, and the 12 month dental visit. The in-person MI session will be approximately 30 minutes. It will be followed by one telephone session within six weeks of the first counseling session.

**Estimated Time to Complete Enrollment:**

12 – 14 months
**Community-Based Intergenerational Oral Health Study**

**Protocol # 09-016E**

**3 November 2010**

**Schematic of Study Model:**

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**PREGNANT WOMEN**

**Intervention During Pregnancy**
- [Brief MI vs. Traditional Health Education]

**Readiness Status**
- [Contemplation]

**Action**
- [Utilization of Dental Services]

**Primary Outcome**
- [Utilization of Maternal Dental Services]

**Intergenerational OH model 5/09**

**Oral Health Impact; Dental Anxiety; Perinatal Depression; Perceived Stress**

**Delivery**

---

**MOTHERS AND CHILDREN**

**Intervention Postpartum**
- [Brief MI vs. Traditional Health Education]

**Readiness Status**
- [Contemplation]

**Action**
- [Utilization of Preventive Dental Services; Engage in Preventive Behaviors]

**Primary Outcome**
- [Utilization of Child Preventive Dental Services]

**Mother’s Oral Health Self-Efficacy, Fatalism, Knowledge, Dental Anxiety; Child Oral Health Impact; Child Oral Hygiene and Dietary Practices**
1 KEY ROLES

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2 BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

2.1 Background Information

Dental Health is an Intergenerational Problem in High Risk Communities

Rural mothers who report good dental health and believe in the benefit of dental care for their children are five times more likely to have a usual source of care for themselves than mothers who report both poor oral health and more negative attitudes (Skaret et al., 2001). Moreover, when rural teenagers with severe tooth decay were compared to controls with similar but restored teeth, a lack of regular visits by the mother discriminated between the groups (Skaret et al., 2004). Kinirons and McCabe (1995) reported similar findings. The parent is the gatekeeper, controlling the child’s access to professional services and making decisions regarding diet and hygiene. Parental perception of the utility of maintaining the primary dentition appears to influence these behaviors. Only recently have professionals established the recommendations to seek dental services beginning in early childhood (AAPD, 2004; Hale, 2003). The public’s knowledge lags behind, with the poor least aware of new approaches. Fewer than one percent of children have such a visit. Most of these rare visits are for unintentional injuries. The percentage of pregnant women who utilize dental care is low. Many women fail to see the importance of oral care during pregnancy, while others experience barriers to care (e.g., lack of dental coverage, limited access to care) (Breedlove, 2004). Foreign- and U.S.-based studies have examined dental utilization by pregnant women and their reasons for not utilizing dental services (Roger, 1991; Mangskau et al., 1996; Gaffield et al., 2001; Habashneh et al., 2005; Lyndon-Rochelle et al., 2005). Socioeconomic status (SES) has a significant association with utilization; low SES women are more likely not to utilize care (Mangskau and Arrindell, 1996; Gaffield et al., 2001; Habashneh et al., 2005; Lyndon-Rochelle et al., 2005). Reasons for not utilizing were: unnecessary, work/family commitments, fear, not liking the dentist, forgot/lazy, and illness (Roger, 1991).

Continuity of care, defined as consistent, longitudinal care, is accepted as a “cornerstone of primary care.” It has been shown to impact patient satisfaction, medication compliance, and to
minimize behavioral problems (Jee and Cabana, 2006). Continuity of care for children has been found to be associated with improved utilization of health services, improved health outcomes, and preventive care (Alpert, et al., 1976; Mainous, et al., 1998; Christakis et al, 2000, 2001, 2004). Counseling parents about tooth decay in settings without continuity has met with minimal success (Berkowitz, et al., 1997). However, many people, especially those who have not had regular positive contacts with dental health providers, have the commonsensical belief that when their teeth do not hurt them, there are no problems that require attention (Varenne et al., 2006; Bedos et al., 2005). Leventhal and others (2003, 4) proposed the Common Sense Self-Regulation Model to explain beliefs and behaviors in diseases that have symptomatic and asymptomatic parts. The model of illness is based on experience with acute illness; these experiences encourage people to think of illness as acute episodes rather than chronic conditions, thus utilizing services in a similar way. While continuity of care is acknowledged as critical for prevention of disease in children, there is “discontinuity” between mother’s and children’s dental care and their dental benefits, particularly for the Medicaid population. New York State published guidelines for treating pregnant women (Burakoff, 2006). Despite these guidelines, there appears to be misinformation and discomfort in providing dental treatment to pregnant women and their children (Shrout et al., 1994; Pistorius et al., 2003; Turner et al., 2006).

**Alternative Constructs May Lead to More Effective Strategies**

The application of theories of behavior and behavior change will lead to a better understanding of utilization. According to the Transtheoretical (Stages of Change) model of change (Prochaska and DiClemente, 1984; Prochaska et al., 1994), people pass through a process as they move from not accepting the need to change a behavior (precontemplation) to accepting the need (action) to maintain the behavior change (maintenance), suggesting that those who think of dental health in terms of acute care are at the precontemplation stage. The importance of this model lies in the fact that strategies and activities to promote change differ significantly across stages (DiClemente et al., 1991). The Common Sense Self-Regulation model is compatible with the Stages of Change model. People at the precontemplation stage do not recognize the need to change. Mismatch of patient stage and treatment strategy is predicted to increase patient resistance to change and to undermine therapeutic outcomes (Wilson and Schlam, 2004). Stage status is also useful in predicting an individual's proximity to behavior change and the
amount of effort required to move her/him into action (Martin et al., 1996). Motivational interviewing, a client-centered but directive counseling approach, utilizes the Stages of Change theory in formulating interventions (Miller and Brown, 1991). Self-regulation models view people as actively involved in attempts to reduce gaps between perceived current status and immediate and long-term goals. Health and illness behaviors are the result of a person’s representation of health threats and perceptions of the relevance of actions for managing or controlling these threats (Leventhal, 1993). The approach builds on client-centered counseling skills (Rogers, 1970). Brief MI (BMI) was designed for use in primary health care settings where overworked providers have little time with each patient. A meta-analysis of 11 studies using BMI (defined as an encounter less than 20 minutes) found that 64% showed an effect (Rubak et al., 2005). BMI has been used successfully in prenatal settings (Handmaker and Wilbourne, 2001; Jones, et al., 2004). Motivational Enhancement Therapy (MET), a type of BMI, engages the patient in a highly structured assessment of risk and provides normative feedback, a menu of change options, and follow-up (Lawendowski, 1998; Carroll et al., 2002).

PRELIMINARY STUDIES

Brief Motivational Interviewing (BMI) With Mothers Can Reduce Tooth Decay in Their Children
Weinstein and others (2004, 6, 7) have used BMI to control dental disease. They studied 240 high-risk infants aged 6 to 18 months and their parents. Parents were randomly assigned to a BMI provided by a trained local woman or traditional health education intervention. BMI took 45 minutes and included six follow-up phone calls and two postcards over a year. BMI focused on home oral hygiene and dietary habits. There was a 46% reduction in the incidence of caries in the BMI group (Hazard Ratio = 0.54, 95% CI=0.35, 0.84) after two years.

A Regular Source of Dental Care among Mothers Increases the Probability of a Child Having a Preventive Dental Visit
In this study of Medicaid mothers of preschool-aged children in Washington State, Grembowski, Milgrom, and Spiekerman (2008) investigated the probability of a child having a dental visit when his/her mother did or did not have a usual source of care. The study found that, all other things equal, Medicaid enrolled children whose mothers had a usual source of dental care were 1.5 times more likely to have a dental visit than children with mothers who lacked a regular source of care.
Simple Intervention Boosted Utilization by Pregnant Low-Income Women and Improved the Health of Their Children

Klamath County, Oregon conducted a community-based intervention program to promote dental visits through provision of a dental home for pregnant women covered by Medicaid (Milgrom et al., 2008). Pregnant women received home or WIC visits by a dental hygienist and were assigned a dental home under a managed care program. Overall, 55.8% of eligible women received dental care compared to less than 9% statewide. Preliminary follow-up showed ~93% of the infants of the mothers who used care were caries free at 2 years old.

Identified Barriers to Using Dental Care During Pregnancy among Low-Income Women

A qualitative study using structured telephone interviews (Le, Riedy, Milgrom & Weinstein, 2009) was conducted to understand factors influencing why eligible pregnant women in the program described above used or did not use dental care. The interviews asked about stress and dental-related issues within a Stages of Change conceptual model to determine if these factors prevented or encouraged movement toward the action of going to the dentist. Stress during pregnancy included internal (physical and emotional) and external factors (i.e., personal relationships, finances, employment status, surroundings). Dental-related issues included internal (perceptions about dental experiences, attitude toward dentist, valuing oral health, importance of dental health) and external influences (finances, time, attitude of dentist). These data can be used to improve this type of program.

Survey of Oregon Dentists Identifies Positive Attitudes and Need for Continuing Dental Education

Center investigators, Milgrom, Huebner and others, recently conducted a statewide survey of licensed Oregon dentists to understand the needs of dental providers responsible for providing care to pregnant women (Huebner et al., 2009). Almost all dentist respondents (93%) believed dental care should be part of prenatal care, and 78% felt they had the skills to counsel pregnant women. However, almost half (42%) were concerned with being sued if something were to go wrong in the pregnancy. Very few had received continuing dental education in providing oral health care for pregnant women or young children (28%, 44%, respectively). And less than a third (30%), reported giving information about maternal-child transmission of caries to all of their pregnant patients.
Conclusions from the Background and Significance and Preliminary Studies

- We conducted the first US demonstration project in rural communities to show promising results in increasing the number of pregnant women who sought dental care. Barriers to care were identified. Preliminary follow-up showed ~93% of the infants of the mothers who used care were caries free at 2 years old.

- Use of dental care to prevent tooth decay is an intergenerational problem. A young child’s primary caretaker has control over many of the behavioral factors that determine whether or not the child develops cavities. Interventions that focus on the perinatal period are a high priority for public health.

- Interventions that focus solely on knowledge will be insufficient to overcome the commonsense point of view. However, employing interventions with an underlying behavioral theory promises to increase the effectiveness of the interventions further. A regular source of care during and after pregnancy is important for reducing children’s oral health disparities.

- The relatively few studies examining health providers’ knowledge and skills with providing dental care during pregnancy suggest both dentists’ openness and the need for more continuing education.

2.2 Rationale

*Rural Healthy People 2010* identified oral health as number 5 in a top ten of rural health priorities. Vargas, Ronzio, and Hayes (2003) found that poor children in rural areas had greater unmet dental needs and less access than poor urban children. They reported rural residents were less likely to report a dental visit in the previous year and more likely to report their last visit was because something “was bothering or hurting.” We conceptualize the prevention of childhood caries as having two important stages: 1) reducing the transmission of pathonomic bacteria from mother to child and 2) providing preventive dental care for the child at an early age. Delaying infection of the child by the mother reduces child tooth decay (Kohler et al., 1984; Kohler, Andreen, 1994). Preventive dental programs targeting pregnant women can be effective (Gunay et al., 1998; Gomez et al., 2001; Isohanka, 2000). Long-term preventive programs (pre- and post-natal) for mothers and children showed improvements in oral health and lower rates of tooth decay in the children (Gunay et al., 1998; Gomez et al., 2001). Nevertheless, the
percentage of low-income women who utilize dental care in the perinatal period is astoundingly low (e.g., in Oregon ~ 9%; Milgrom et al., 2008).

**Study Hypotheses:**

H1: Mother’s utilization: Women who receive MI *during* pregnancy will have a greater frequency of utilization of dental care during pregnancy than women who receive traditional health education *during* pregnancy.

H2: Children’s utilization: Children whose mothers receive MI *after* pregnancy will have a greater frequency of utilization of preventive dental care during the first 18 months of life than children whose mothers receive traditional health education *after* pregnancy.

H3: Children’s utilization: Children whose mothers receive MI *before and after* pregnancy will have a greater frequency of utilization of preventive dental care during the first 18 months of life than children whose mothers were receive traditional health education during pregnancy and MI *after* pregnancy.

**2.3 Potential Risks and Benefits**

**2.3.1 Potential Risks**

The Brief MI counseling sessions are of minimal risk. The goal of the in-person and telephone sessions is to assist the pregnant woman or mother in being able to access needed dental care. There may be some embarrassment discussing barriers to receiving care. Additional risks to the study subjects would be embarrassment or discomfort in answering items on questionnaires to be completed at specified intervals over the course of the study. Subjects will be instructed not to answer any questions that they feel uncomfortable with. All data will be confidential so the risk to the participant will be minimal. Data (audiotapes, transcripts, questionnaires) will be stored separately from identifying information and kept in a locked file cabinet or password-protected computer.
2.3.2 Known Potential Benefits

The intervention will have a direct benefit to the subjects. The benefit for participating is that subjects may gain increased access to dental care and reduced barriers to utilization. All subjects will receive an incentive for their participation in the study. Society will benefit if the results of the study are used to strengthen effective programs and inform public policy.
3 OBJECTIVES

3.1 Study Objectives
The aim is to test a community-based intervention trial using brief motivational interviewing provided to low-income women during the prenatal and/or postpartum period(s) to; (1) increase utilization of dental care during pregnancy or the postpartum period, and (2) increase utilization of preventive dental care by their young children.

3.2 Study Outcome Measures

3.2.1 Primary Outcome Measures
The primary outcome measures for the study will be dental utilization during pregnancy and up to two months postpartum for the mother, and preventive dental utilization by 18 months for the child. These outcomes will be measured through the Medicaid claims database to be obtained from the Oregon Division of Medical Assistance Programs (DMAP) which is part of the Department of Health and Human Services (DHHS) and is in charge of the Oregon Medicaid claims database. The data we will receive from DMAP will include all claims related to dental procedures covered under OHP by Current Dental Terminology (CDT) codes. For example in the primary outcome measures of interest, within the OHP-defined category of health services, Preventive Dental Services (CDT codes - 100s, 1000s), routine and problem-based dental exams, cleanings, and fluoride treatments would be found.

3.2.2 Secondary Outcome Measures
The two secondary outcome measures for the study will be 1) number of preventive home oral health practices taken by mothers to prevent caries in their young children, and 2) readiness to change. The first outcome, number of home oral health practices by the mother, will be assessed using survey measures/questionnaires (Finlayson et al., 2005; Evens, 1997). The second outcome, readiness to change, will be assessed using a Readiness Ladder modified for this study. The primary outcomes, described above, will be mediated by the woman’s readiness to change, which will result from the interventions. Mediating variables or intervening factors
may be an underlying mechanism for achieving the outcome or behavior. Moderators to readiness to change will also be assessed. Moderating variables are individual characteristics that may modify the relationship among the readiness variable. Within pregnancy stage, the variables such as perinatal depression (Center for Epidemiologic Studies Depression Scale (CES-D) Radloff, 1977), perceived stress (Perceived Stress Scale (PSS) Cohen et al., 1983; Cohen & Williamson, 1988), oral health impact (Oral Health Impact Profile short form (OHIP) de Oliveira, Nadanovsky, 2006), and dental anxiety questions (M-DAS) Humphris et al., 1995) will be assessed. Within the motherhood stage, the variables such as dental anxiety of the caregiver (Humphris et al., 1995), self-efficacy, oral health knowledge, fatalism (Adair et al., 2004; Finlayson et al., 2005), and child oral health impact (Pahel et al., 2007) will be assessed.
4 STUDY DESIGN

This section describes the model and design of the intervention study. The study will utilize a four-group, multi-site, single-blind, randomized trial design (Phase 3).

4.1 Study Participants

Subjects will be 400 pregnant women and their live born children living in four rural Oregon counties. To be eligible for the study, at enrollment women will be in the first or second trimester of their pregnancy and be eligible for coverage on the Oregon Health Plan (OHP), specifically OHP Plus (for pregnant women). OHP provides medical and dental services to adults and children enrolled in Medicaid. Dental care is available as an OHP benefit and dentist accessibility has been established through the statewide dental care organizations. The first and second trimesters were selected to give us the longest time period to deliver the pregnancy-focused intervention. This study will be limited to English speakers as they make up the largest percentage of county residents (See Table 4.1). We also determined in our planning that many Spanish-speaking women on OHP did not have full (medical and dental) coverage.

Table 4.1.1 County Population

<table>
<thead>
<tr>
<th>County</th>
<th>Population</th>
<th>%Non English</th>
<th>Medicaid (OHP) Births/Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Josephine</td>
<td>81,688</td>
<td>4.8</td>
<td>505</td>
</tr>
<tr>
<td>2 Lincoln</td>
<td>46,199</td>
<td>5.7</td>
<td>278</td>
</tr>
<tr>
<td>3 Douglas</td>
<td>105,117</td>
<td>3.9</td>
<td>664</td>
</tr>
<tr>
<td>4 Jefferson</td>
<td>20,352</td>
<td>19</td>
<td>223</td>
</tr>
</tbody>
</table>
4.2 Model and Design

Figure 4.2.1 shows the study model for the intervention. There is not much of a literature that specifies MI theory. Recent articles (Miller and Rose, 2009; Apodaca and Longabaugh, 2009) point to promising treatment variables that may account for change (MI spirit and variables related to change talk). MI theory does not lend itself to a model that focuses on subject variables. Therefore, we will employ the Stages of Change model (Prochaska and DiClemente, 1984) under the rubric of MI to develop our model. There are two life stages addressed in this study: pregnancy and motherhood. Each is represented in the model. The study begins in pregnancy when the focus of the study is the pregnant woman. Two interventions are delivered at this stage – women receive either 1) pregnancy-focused (prenatal) traditional health education materials or 2) brief motivational interviewing (MI). The study then continues into motherhood where the focus of the study is both mother and child. Similarly to the pregnancy stage, there are two groups – women receive either 1) child-focused (postpartum) traditional health education materials or 2) brief MI. Thus, this is a 4-group design with women randomly assigned in pregnancy to receive MI or traditional health education in pregnancy and MI or traditional education postpartum.

The primary outcome measure for the pregnant woman is dental utilization during pregnancy and up to two months postpartum. The outcome will be mediated by readiness to change which will result from the MI intervention. Mediating variables or intervening factors may be an underlying mechanism for achieving the outcome or behavior. The moderating variables are oral health quality of life, dental anxiety, perinatal depression, and perceived stress which are individual characteristics that may modify the relationship among the variable readiness to change. The primary outcome measure for the child is preventive dental utilization by 18 months of age. Similar to the first stage, this second stage’s outcome is mediated by readiness which can be moderated by several variables including mother’s self-efficacy for providing children’s oral hygiene, fatalism, knowledge, and dental anxiety.

The primary outcome measurement data (pregnant women; children) will be obtained through the DMAP Medicaid claims database. The data from DMAP will be requested three times; once for the mother’s data and twice for the child’s data. The mother’s data will be requested at the end of the follow-up period (i.e., three months after the birth of the last enrolled participant). The child’s data will be requested twice, 12 months after the birth of the last enrolled participant and
18 months after the birth of the last enrolled participant. The secondary outcome measurement (moderating variable data) will be collected through questionnaires completed at baseline (prior to birth), and 3, 9, and 18 months (months after birth, respectively).

**Figure 4.2.1 Study Model Schematic**

Table 4.2.1 describes the four groups and the sample size of each group. The intervention will be a mother-child focused (prenatal-postpartum) brief Motivational Interviewing (MI) counseling
intervention provided to low-income women in four rural Oregon counties. The first part will be focused on pregnant women (prenatal MI); the second part will be aimed at their live born children (postpartum MI). The table shows a 2 x 2 factorial design where each participant is randomized at enrollment to one of four groups - to receive either the Prenatal MI or Traditional Health Education and further to receive Postpartum MI or Traditional Health Education. As previously described, women are assigned in pregnancy to receive MI or traditional health education in pregnancy and MI or traditional education postpartum.

This type of design allows us to simultaneously test two different hypotheses (i.e., MI counseling given during pregnancy; MI counseling given during early childhood), as well as more effectively examining the additional effect of MI given during pregnancy and postpartum.

### Table 4.2.1 Four Group Design

<table>
<thead>
<tr>
<th>Pregnancy (Prenatal) MI</th>
<th>Child (Postpartum) MI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Group 1</td>
</tr>
<tr>
<td></td>
<td>(Prenatal MI - Postpartum MI)</td>
</tr>
<tr>
<td></td>
<td>N=148</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Group 2</td>
</tr>
<tr>
<td></td>
<td>(Prenatal MI – Postpartum Traditional Health Ed)</td>
</tr>
<tr>
<td></td>
<td>N=52</td>
</tr>
<tr>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Group 3</td>
</tr>
<tr>
<td></td>
<td>(Prenatal Traditional Health Ed – Postpartum MI)</td>
</tr>
<tr>
<td></td>
<td>N=148</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Group 4</td>
</tr>
<tr>
<td></td>
<td>(Prenatal Traditional Health Ed – Postpartum Traditional Health Ed)</td>
</tr>
<tr>
<td></td>
<td>N=52</td>
</tr>
</tbody>
</table>

Traditional Health Education: The control group in our study will receive a modified Traditional Health Education. The prenatal education materials are written materials published by the National Maternal Child Oral Health Resource Center (NMCOHRC; “Two Healthy Smiles”) supplemented with a brief video (~10-15 minutes) that covers the information in the written pamphlet. Women will also receive information about using their dental care coverage,
guidelines to being a successful dental patient, and a “prescription” for good oral health care. These materials were created or modified for this study.

The postpartum materials are written materials published by the National Maternal Child Oral Health Resource Center (NMCOHRC; “Two Healthy Smiles”, “A Healthy Smile For Your Baby”, and ”A Healthy Smile For Your Young Child) and also from NMCOHRC (“Topical fluoride recommendations for high risk children”). A supplemental video will also be provided (~10-15 minutes) on preventing early childhood dental decay. We will also include the “prescription” for good oral health care again.

Brief Motivational Interviewing (BMI) Intervention: The MI intervention will involve brief counseling and follow-up with the use of materials that motivate and provide choices among community-recommended strategies to utilize preventive dental services and engage in home care activities to prevent tooth decay provided by local trained women in a Women, Infants, and Children (WIC) or public health (PH) setting. Participants will also receive the traditional health education materials as described above for each stage.

The prenatal MI participants will receive one-to-one in-person counseling during pregnancy (after enrollment). The counselor will identify their dental needs, their dental risks, reinforce their dental needs, and navigate barriers to care. During the first MI visit, the counselor will utilize both a written and electronic protocol (~30 minutes) to deliver the intervention. Within six weeks of the in-person session, the counselor will provide two follow-up telephone sessions. Additionally, participants will receive a phone call 1 month prior to birth. Its purpose is to inquire about their pregnancy as well as dental issues.

The postpartum MI participants will receive their first child-centered MI session at 9 months post-partum. The content will focus on the child and include preventive strategies such as oral hygiene and dietary practices, and the 12 month dental visit. The in-person MI session will be approximately 30 minutes. It will be followed by one telephone session within six weeks of the first counseling session.

Figure 4.2.2 shows the timeline of the study including the anticipated time to complete recruitment and enrollment (~ 14 months), time to complete data collection (Year 5, 6th month), and time to complete the study (end of Year 5). The duration for participation for each subject will be approximately 24 months (up to 6 months during pregnancy; 18 months after birth).
Figure 4.2.2 Timeline

4.3 Structure for Safety Oversight

Per the NIDCR guidelines this study’s oversight structure will be a Clinical Science Oversight Committee (CSOC). The CSOC will be appointed by NIDCR.
5 STUDY ENROLLMENT AND WITHDRAWAL

5.1 Subject Inclusion Criteria
All pregnant women who are eligible for OHP will be eligible for the study except for those who meet any of the exclusion criteria described in the next section, Section 5.2 Subject Exclusion Criteria.

The County Counselor will contact each woman to speak with her about the study (Refer to section 5.2 – Mechanism of Recruitment). The sections on inclusion and exclusion criteria will be completed after the woman is told about the study and the consent form is reviewed (Refer to section 5.1.1 – Eligibility Checklist Form). If the woman meets all of the inclusion criteria and none of the exclusion criteria then she is eligible to be enrolled in the study. The County Counselor will inform her about the study procedures, etc. by going over the consent form (Refer to section 14.3 – Informed Consent Process). If the expectant woman gives informed consent she will be randomized.
5.1.1 Eligibility Checklist Form
Baby Smiles: Screening Form

Screening Information

County
☐ Douglas    ☐ Josephine
☐ Jefferson  ☐ Lincoln

Date ______ / ______ / ______

Time: ______________________

Location: ______________________

Counselor: ______________________

Subject Information

Last name ______________________

Age ______________________

First name ______________________

Due date ______ / ______ / ______

Address ______________________

City, State, Zip ______________________

Phone ______________________

Email ______________________

Contact preferences ______________________

Eligibility Criteria

☐ Pregnant (week 26 or earlier)

☐ At least 15 years of age

☐ OHP eligible: OHP # __________

☐ Speaks English

☐ Willing and able to comply with study instructions

☐ Mother AND child available for length of the study

Consent

Mother willingly gave informed consent?

☐ Yes

☐ No

☐ Other

If “No” or “Other” please specify: ______________________

County

Date ______ / ______ / ______

☐ Douglas

☐ Josephine

☐ Jefferson

☐ Lincoln

Counselor: ______________________

Subject Information

Last name ______________________

Age ______________________

First name ______________________

Due date ______ / ______ / ______

Address ______________________

City, State, Zip ______________________

Phone ______________________

Email ______________________

Contact preferences ______________________

Eligibility Criteria

☐ Pregnant (week 26 or earlier)

☐ At least 15 years of age

☐ OHP eligible: OHP # __________

☐ Speaks English

☐ Willing and able to comply with study instructions

☐ Mother AND child available for length of the study

Consent

Mother willingly gave informed consent?

☐ Yes

☐ No

☐ Other

If “No” or “Other” please specify: ______________________
Enrollment
Study ID#: ______________________

Study Group

☐ Prenatal MI  ☐ Prenatal ED

Alternate Contact Information

Baby Smiles: Screening Form (continued)

Alternate Contact Information

Last name ______________________  Relationship to subject ______________________
First name ______________________
Address ______________________
City, ST, Zip ______________________
Phone ______________________
Email ______________________

Last name ______________________
First name ______________________
Address ______________________
City, ST, Zip ______________________
Phone ______________________
Email ______________________
Last name ____________________________  Relationship to subject ____________________________
First name ____________________________
Address __________________________________________________________
City, ST, Zip _________________________________________________________
Phone ______________________________________________________________
Email _______________________________________________________________
5.2 Subject Exclusion Criteria

We will exclude: expectant mothers who are not 15 years or older, do not speak English, and expectant mothers who will not have their baby residing with them through the length of the study.

5.3 Strategies for Recruitment and Retention

All subjects will be recruited in Oregon State and will be volunteers. Recruitment will be a multi-pronged approach. Primary recruitment will come through posted flyers/leave behind cards in the four intervention counties health departments/WIC settings (Women, Infant, Child) as well as at prenatal care providers in the community and other community agencies whose clientele are pregnant women. Recruitment will also be done in-person through the WIC staff mentioning the study to their clients within the WIC setting and pregnancy test department within the public health departments.

Each county’s public health department will employ a counselor (referred to as a County Counselor) to enroll study subjects and to perform the study procedures. The County Counselor will work with the WIC staff to identify potentially eligible pregnant women. WIC staff as well as other prenatal care providers will provide interested women with study contact information and will refer women to the County Counselor if they are interested.

5.4 Treatment Assignment Procedures

5.4.1 Randomization Procedures

Participants will be randomly assigned to one of the four intervention groups using computer-generated permuted blocks of varying block sizes to ensure that the study groups will be proportionally balanced across study period and within each county and counselor. The randomization procedure will be stratified on county and counselor. Study group proportions are listed in Table 4.2.1. The study Biostatistician will create the randomization procedure and the study Data Manager will generate the random intervention-assignment lists for each county and counselor.
After the subject has given informed consent and been enrolled in the study, the County Counselor will inform the subject of her randomly generated study group assignment. The County Counselor will be blinded to the study group assignment prior to informing the subject. The master randomization list will be retained by only the Data Manager.

5.4.2 Masking Procedures

Since this is a single-blind study, all study participants will be blinded to the interventions but not the local study team (i.e., County Counselor) or the Co-Principal Investigators.

The Data Manager will assign the codes to the intervention groups to maintain masking of all study personnel, including the Biostatistician, for reports on study enrollment and follow-up aggregated by county, as well as for data summaries aggregated by study group.

The codes may be broken for the following reasons:

1. At the request of the CSOC and IRB, to investigate a serious adverse effect or unanticipated problem.

2. For interim reviews of the data by the CSOC, to determine if an effect of the intervention has been ascertained prior to the fulfillment of enrollment targets.

In addition, since the study has two parts, we may unmask the study groups after all the prenatal data is collected in order to report preliminary results at a conference. The Data Manager and Biostatistician will consult with the Co-Pis before breaking study codes for aggregate or individual level analysis.

5.4.3 Reasons for Withdrawal

A participant may stop taking part in the study at any time or be discontinued by study personnel.

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

Participants may also be withdrawn (or discontinued) from the study by study personnel if the
subject becomes ineligible or for other reasons (e.g., miscarriage or loss of child custody).

Participants who are discontinued from the study by one of the study personnel will be considered a discontinuer.

5.4.4 Handling of Withdrawals

A tracking database will be maintained by each County Counselor to track and update any dropouts/withdrawals and discontinuers (as well as maintaining information on continuing participants). All participants' information will be entered into the database which will be kept on PASSWORD-PROTECTED computers. The database file will also be PASSWORD-PROTECTED. The County Counselor and Data Manager will know the passwords. The County Counselor will be responsible for maintaining and updating the tracking database.

All reasons for dropout/withdrawal or discontinuation of the study intervention will be documented in the tracking database and reviewed by the study team and CSOC. For gathering information on discontinuation, County Counselors will be contacting participants regarding birth outcomes as miscarriages will not be on the birth record.

In the event of a participant telling the Counselor that she is dropping out of the study, the Counselor should gather the following information as much as the participant allows.

- Record the reason for dropping out of the study.
- Record any unanticipated problems as reported by participant.
- Debrief about the prenatal or postpartum intervention.
- Complete the appropriate questionnaire nearest the drop out time point.

If it is determined by study personnel that a participant should be discontinued from the study, the decision to withdraw a participant must be discussed and confirmed by both the Counselor and study Co-PI’s. If both the Counselor and study Co-PI’s agree that a participant should be withdrawn from the study, the date of withdrawal and reason(s) for withdrawal should be recorded in the tracking database by the Counselor. For gathering information on discontinuation, Counselors will be contacting participants regarding birth outcomes as miscarriages will not be on the birth record.
5.4.5 Termination of Study

Termination of the study normally would occur at the end of subject accrual and completion of all study procedures. For various reasons a study may terminate prematurely. Possible reasons for terminating the study early are study closure due to CSOC or IRB review and the discretion of NIDCR, the funding agency.
6 STUDY INTERVENTION

6.1 Study Intervention Description

This study will utilize a 2 x 2 model for the study intervention (see Table 6.1 below); the first level is when the intervention will be delivered (prenatal vs. postpartum) and the second level is what type of intervention will be delivered (brief motivational interviewing (MI) counseling session vs. traditional health education materials session).

Table 6.1

<table>
<thead>
<tr>
<th>1st level</th>
<th>2nd level</th>
<th>Child (Postpartum)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnancy (Prenatal)</td>
<td>MI</td>
<td>Health Education Materials</td>
</tr>
<tr>
<td>MI</td>
<td>Group 1</td>
<td>Group 2</td>
</tr>
<tr>
<td>Health Education Materials</td>
<td>Group 3</td>
<td>Group 4</td>
</tr>
</tbody>
</table>

The study intervention will be a brief motivational interviewing (MI) counseling session with several follow-ups. Follow-up contacts are dependent on the period in which the MI session is delivered (prenatal vs. postpartum) and will be described below. The control condition (or standard of care) will be a traditional health educational material session and follow-ups. The intervention protocols will differ for the prenatal and postpartum delivery of the MI intervention as the purposes of the counseling within these two periods are different. The study intervention and control groups will be administered by the County Counselor. This section will describe the MI counseling sessions given during the prenatal period and during the postpartum period as well as the control conditions within these two periods.

MI Intervention

Overall, the MI intervention will involve counseling and follow-up contacts with the use of materials that motivate and provide choices among community-recommended strategies to
utilize preventive dental services and engage in home care activities to prevent tooth decay provided by local trained women in a Women, Infants, and Children (WIC) or public health setting. Participants will also receive the traditional health education materials as described below. Refer to Section 7 Study Schedule (and Appendix A Schedule of Events) for the intervention/control timeline of visits and follow-up contacts.

**Prenatal MI Intervention**

In the prenatal MI intervention one-to-one in-person counseling delivered by the County Counselor will be provided after pregnant women have consented to and been enrolled in the study. The counselor will identify their dental needs, their dental risks, reinforce their dental needs, and navigate barriers to care. During the first MI visit, the counselor will utilize both a written and electronic protocol (~30 minutes) to deliver the intervention. Refer to Section 8 Study Procedures (Prenatal MI Protocol) for the protocol elements.

**Postpartum MI Intervention**

In the postpartum MI intervention one-to-one in-person counseling delivered by the County Counselor will be provided to the postpartum women nine months after birth. The content will focus on the child and include preventive strategies such as oral hygiene and dietary practices, and the 12 month dental visit for the child. The counselor will identify their needs for their child’s dental health, the dental risks for their children, reinforce their needs, and navigate barriers to professional and personal care. During the first MI visit, the counselor will utilize a written protocol (~30 minutes) to deliver the intervention. Refer to Section 8 Study Procedures (Postpartum MI Protocol) for the protocol elements.

**Control Condition**

**Prenatal Control Condition**

The prenatal materials will be from the National Maternal Child Oral Health Resource Center (NMCOHRC; “Two Healthy Smiles”) including a computerized slide show outlining the pamphlet. During the first control visit, the County Counselor will utilize a written protocol (~30 minutes) to deliver the intervention. Women will also receive information about using their
dental care coverage, guidelines to being a successful dental patient, and a “prescription” for good oral health care.

Postpartum Control Condition

The postpartum materials are written materials published by the National Maternal Child Oral Health Resource Center (NMCOHRC; “Two Healthy Smiles”, “A Healthy Smile For Your Baby”, and "A Healthy Smile For Your Young Child) the NMCOHRC (“Topical fluoride recommendations for high risk children”), and a video on preventing early childhood dental decay. During the first postpartum control condition, the County Counselor will utilize a written protocol (~30 minutes) to deliver the intervention nine months after the child is born. We will also include the “prescription” for good oral health care again.

6.2 Modification of Study Intervention for a Participant

Modifications to the study intervention will not be done on an individual basis but for the entire study population as deemed necessary. All modifications will be submitted and approved by NIDCR, the Oregon PH IRB, and the UW IRB prior to being implemented.

6.3 Accountability Procedures for the Study Intervention/Investigational Product(s)

Accountability procedures will be described in Chapter 10 – Clinical (or Fidelity) Monitoring.

6.4 Concomitant Medications/Treatments

All concomitant medications and treatments are allowed.
7 STUDY SCHEDULE

Refer to Appendix A for the Schedule of Events.

7.1 Screening

Screening Visit (Day -14 to 0)

- Contact interested potential participants by telephone or in person to screen for their eligibility.
- Review Eligibility Checklist Form (Refer to Section 5.1.1) to determine eligibility based on inclusion/exclusion criteria.
- Review the written consent form (Refer to Section 14.3.1) with the potential participant; counselor signs the consent form acknowledging that informed consent was reviewed.

7.2 Enrollment/Baseline

Enrollment/Baseline Prenatal Visit - Prenatal Period (Visit 1, Day 0)

- Obtain signature of eligible, potential participant on informed consent form if interested in the study.
- Randomize eligible participant to 1 of 4 groups.
- Obtain demographic information including dental history, obtain responses to the following questionnaires; Oral Health Impact Profile – short form (OHIP14), Modified Dental Anxiety Scale (MDAS), Pregnancy Readiness Ladder (PRL); pre-post), Perceived Stress Scale (PSS), Center for Epidemiologic Studies Depression Scale (CES-D)
- Administer the protocol (Traditional Health Education Materials or MI) to each participant depending on assigned group.
- Schedule follow-up visits (telephone contacts) with the participants 4 and 6 weeks after the baseline interview.
Baseline Postpartum Visit - Postpartum Period (Visit 1, 9 months postpartum)

- Record any adverse events as reported by participant.

- Obtain updated demographic information including dental care, obtain responses to the following questionnaires:
  
  - for the mother; Perceived Stress Scale (PSS), Center for Epidemiologic Studies Depression Scale (CES-D)
  
  - for the child; (Child Readiness Ladder (CRL), Modified Dental Anxiety Scale (MDAS-caregiver), child oral health impact (ECOHIS), oral health self-efficacy (OHSE), oral health-related fatalism (OHF), knowledge of bottle use (KBU) and children’s oral hygiene (KCOH), and dietary and oral hygiene practices).

- Administer the protocol (Traditional Health Education Materials or MI) to each participant depending on assigned group.

- Schedule follow-up visits (telephone contacts) with the participants 6 weeks after the baseline postpartum interview.

7.3 Follow-up

Follow-up Visit - Prenatal Period (Visit 1, 4 weeks after baseline)

- Telephone contact 4 weeks after the baseline/initial visit to check in

- Record any unanticipated problems as reported by participant.

- Administer follow-up counseling (if needed) for MI group.

Follow-up Visit - Prenatal Period (Visit 2, 6 weeks after baseline)

- Telephone contact 6 weeks after the baseline/initial visit to check in

- Record any unanticipated problems as reported by participant.

- Administer follow-up counseling (if needed) for MI group.

Follow-up Visit - Prenatal Period (Visit 3, 1 month prior to due date)
• Postcard contact 1 month prior to birth to check in

Follow-up Visit - Prenatal Period (Visit 4, 1 week after due date)
• Telephone contact 1 week after due date to check in
• Record any unanticipated problems as reported by participant.

Follow-up Visit - Prenatal Period (Visit 5, 3 months postpartum)
• Obtain updated demographic information including dental care, obtain responses to the following questionnaires:
  o for the mother; Oral Health Impact Profile – short form (OHIP14), Perceived Stress Scale (PSS), Center for Epidemiologic Studies Depression Scale (CES-D)
  o for the child; (Modified Dental Anxiety Scale (MDAS-caregiver), oral health self-efficacy (OHSE), oral health-related fatalism (OHF), knowledge of bottle use (KBU) and children’s oral hygiene (KCOH), and dietary practices).
• Debrief about the prenatal intervention.

Follow-up Visit - Prenatal Period (Visit 6, 6 months postpartum)
• Telephone contact 6 months postpartum to check in
• Record any unanticipated problems as reported by participant.

Follow-up Visit - Postpartum Period (Visit 1, 6 weeks after baseline postpartum visit*)
• Telephone contact 6 weeks after the baseline postpartum visit* to check in
• Record any unanticipated problems as reported by participant.

*The postpartum baseline visit will occur 9 months after the participant has given birth.

7.4 Final Study Visit

Final Study Visit (18 months postpartum)
• In-person contact 18 months after birth

• Record any unanticipated problems as reported by participant.

• Debrief about the postpartum intervention.

• Obtain updated demographic information including dental care, obtain responses to the following questionnaires:
  
  o for the mother; Oral Health Impact Profile – short form (OHIP14), Perceived Stress Scale (PSS), Center for Epidemiologic Studies Depression Scale (CES-D)
  
  o for the child; (Child Readiness Ladder (CRL), Modified Dental Anxiety Scale (MDAS-caregiver), child oral health impact (ECOHIS), oral health self-efficacy (OHSE), oral health-related fatalism (OHF), knowledge of bottle use (KBU) and children’s oral hygiene (KCOH), and dietary and oral hygiene practices).

7.5 Early Termination Visit

Early Termination Visit (any time participant terminates from the study)

• In-person contact

• Record any unanticipated problems as reported by participant.

• Debrief about the prenatal or postpartum intervention.

• Obtain updated demographic information including dental care, obtain responses to the following questionnaires:

  o for the mother; Oral Health Impact Profile – short form (OHIP14), Perceived Stress Scale (PSS), Center for Epidemiologic Studies Depression Scale (CES-D)

  o for the child (if termination is AFTER the postpartum period of the study); (Child Readiness Ladder (CRL), Modified Dental Anxiety Scale (MDAS-caregiver), child oral health impact (ECOHIS), oral health self-efficacy (OHSE), oral health-related fatalism (OHF), knowledge of bottle use (KBU) and children’s oral hygiene (KCOH), and dietary and oral hygiene practices).
7.6 Unscheduled Visit

Section 7.6 is not applicable for this study.
8 STUDY PROCEDURES/EVALUATIONS

8.1 Clinical Evaluations/Counseling Procedures

This section describes the study procedures for the MI counseling both in the prenatal and postpartum periods.

8.1.1 Prenatal MI Counseling Procedures. MI counseling in the prenatal period has four stages.

I. PRECONTEMPLATIVE STAGE: IDENTIFYING MOTIVATION

MI counselors should demonstrate concern and encourage mothers to talk about pregnancy, motherhood, past dental experiences, dental concerns/dental wants for herself or her child.

II. CONTEMPLATIVE STAGE: PROS AND CONS (BENEFITS AND OBSTACLES)

The MI counselor will determine the child’s risk for dental infections and ask the mother many questions about preventing dental disease, the benefits of safety of dental care, obstacles preventing dental care, and dental fear. Up to five videos will be used throughout the MI session to provide information to study participants about these topics. The counselor and participant will problem solve and offer case management when appropriate.

Prenatal MI Intervention Appendices:

Appendix A – Is Your Child At-Risk for Cavities Test
Appendix B – Segment 1 Video; Segment 2 Video
Appendix C – Benefits of Going to the Dentist Ladder & Questions; Segment 3 Video
Appendix D – Dental safety questions; Segment 4 Video
Appendix E – Dental fear; Segment 5 Video
Appendix F – Obstacles
III. PLANNING ACTION STAGE

First step: During this stage, the counselor will summarize where the woman finds herself in relation to the following and ask her to comment on your summary.

- Dental desire for herself and her unborn child
- Whether there is/is not risk
- Assessment of going to the dentist
  - Benefits
  - Safety
  - Fear
  - Other obstacles

Second step: Using open-ended questions, the study participant will be asked what she is willing to do during and after pregnancy with regard to oral health. If the woman seems resistant about making a commitment to go to the dentist, she will be asked about the consequences of not seeking dental care, reminded about what she wants for her child’s oral health, and reminded about the time limitations of her dental insurance.

Third step: The counselor will obtain a commitment to a specific, written plan. The study participant’s commitment will be determined. Resistance will be explored and women will be asked to think about decisions not to seek dental care. A commitment will be made to a written plan for those that are ready.

IV. FOLLOW-UP: SUBSEQUENT FOLLOW-UP CONTACTS

Without follow-up two problems will emerge:

1. The new behaviors will not be tried out because of a problem, or
2. The new behavior will be tried out, but will not be maintained because:
   a. Unanticipated problem(s)
   b. New behavior was never integrated into daily routine and/or there was a relapse.
Follow-up will be made by telephone with post card reminders (See Prenatal MI Intervention Appendices G, H for the follow-up telephone calls).

8.1.2 Postpartum MI Counseling Procedures: MI counseling in the postpartum period has four stages:

I. PRECONTEMPLATIVE STAGE: IDENTIFYING MOTIVATION AND EXPLORING RESISTANCE
MI counselors should demonstrate concern and encourage mothers to talk about their child’s health and welfare, mother and family’s dental health, contact with dentistry, dental experiences, and dental wants/desires for herself and her child. Additionally, counselors will explore the mothers’ resistance to the concepts that baby teeth are important and everyone can have good dental health. The MI counselor will work together with the mother to view the baby’s mouth to further discuss her motivations and dental health wants/desires.

II. CONTEMPLATIVE STAGE: PROS AND CONS (BENEFITS AND OBSTACLES)
MI counselors will share a menu with the mother which provides steps that other parents are willing to do for promoting good oral health in their children. The counselors will review the menu items (Column A (dental visits) and Column B (home oral hygiene and dietary practices) and discuss with the mothers the benefits and obstacles to incorporating that menu item into their lives. Additionally, MI counselors will elicit any other suggestions to include on that mother’s menu.

III. PLANNING ACTION STAGE

First step: During this stage, the counselor will enhance the woman’s commitment to the menu plan by determining who would be supportive.

Second step: Using open-ended questions, the study participant will be asked what she is willing to do to incorporate the selected menu items into her and her child’s life. The three broad areas of the menu are tooth cleaning and fluoride toothpaste, changing feeding and dietary practices, and visiting the dentist (child).
Third step: The counselor will obtain a commitment to a specific, written plan. The study participant’s commitment will be determined. Resistance will be explored and women will be asked to think about decisions not to utilize the menu plan. A commitment will be made to a written menu plan for those that are ready and a copy of the menu will be provided. A brief video will be shown and the mothers will be given brochures.

IV. FOLLOW-UP: SUBSEQUENT FOLLOW-UP CONTACTS

Without follow-up two problems will emerge:

1. The new behaviors will not be tried out because of a problem, or
2. The new behavior will be tried out, but will not be maintained because:
   a. Unanticipated problem(s)
   b. New behavior was never integrated into daily routine and/or there was a relapse.

Follow-up will be made by telephone with post card reminders (See Postpartum MI Intervention Appendices A, B for the follow-up telephone calls).
9  **ASSESSMENT OF SAFETY**

The primary outcomes in this study are dental utilization by the pregnant women and the child obtained from the Medicaid claims database. The secondary outcomes are preventive home oral health practices and readiness to change obtained from questionnaires (Refer to Section 3.2).

9.1  **Specification of Safety Parameters:**

The primary outcome measures: (1) dental utilization from enrollment to two months postpartum for the mother; and (2) preventive dental utilization by 18 months of age for the child. These outcomes will be measured through the Medicaid claims database to be obtained from the [Oregon Division of Medical Assistance Programs (DMAP)](https://www.ohsousedmaps.org) which is part of the Department of Health and Human Services (DHHS) and is in charge of the Oregon Medicaid claims database. The variables to be included in the dataset made available to the study will include all claims related to dental procedures by Current Dental Terminology (CDT) codes for the entire state and associated specific descriptive information including county. The datasets made available to the study team by DMAP will otherwise be de-identified i.e. no other descriptive information such as name, address, or Medicaid or other ID numbers.

The collection of these outcome measures and specific demographic variables pose no physical or mental health safety concerns to the participants. The primary safety concern in obtaining Medicaid claims data from DMAP is the protection of confidentiality of those in the database. As is the policy of DMAP, Medicaid recipients’ confidential information are not be made available to external sources including this study. DMAP will be contracted to provide an overall dataset of the specific requested information and variables noted above. For dental utilization specific to the study participants, DMAP will also provide a sub-dataset where the participants study ID number and Medicaid ID number will be merged with the Medicaid claims data and all identifiable information as specified in the HHS guidelines will be stripped leaving only the specific requested demographic and dental utilization information by CDT code linked to the participants study ID number. This process insures that the confidentiality of those in the datasets provided by DMAP is protected.
The secondary outcome measures will be assessed through a series of questionnaires. The outcome measures and survey tools to be used are as follow: Assessment of perinatal depression (Center for Epidemiologic Studies Depression Scale (CES-D)); Perceived stress (Perceived Stress Scale (PSS)) by pregnant women; Oral health impact (Oral Health Impact Profile short form (OHIP)) and Child oral health impact (Early Childhood Oral Health Impact Scale (ECOHIS)); Dental anxiety questions (M-DAS).

The MI and control interventions/questionnaires present no physical or medical safety risks to the participants. There are two main safety concerns in conducting the intervention and questionnaires. First, the possibility that some questions asked may be perceived by the participants as personal and may elicit some embarrassment or discomfort in answering the items. These safety concerns are of minimal risk criteria. Participants will be instructed prior to the interviews not to answer any questions that they feel uncomfortable with and their responses or non-response to the questionnaire items do not affect their eligibility for health and support services such as medical, dental, WIC, etc. which they are entitled to.

The second safety concern is associated with information (e.g., depression, domestic violence) that is disclosed during the intervention. Participants who disclose information that is a safety concern for themselves or others will be referred for the appropriate services (e.g., clinical counseling) via the respective county’s referral process (e.g., mental health referral process).

Furthermore, to ensure adequate observation and sensitivity are given to the participants during counseling sessions and interviews, County Counselors will be trained to conduct the questionnaires and to give special attention to the participants’ level of comfort with questionnaire items when conducting the counseling or questionnaires (Refer to Section 10 Clinical (or Fidelity of the Intervention) Monitoring.

9.2 Methods and Timing for Assessing, Recording, and Analyzing Safety Parameters

This section defines an unanticipated problem and describes how to report and document their occurrence.
9.2.1 Unanticipated Problems

Definition of 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 (in the guidance document, 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.”

All events meeting the definition of unanticipated problems will be reported according to protocol described below.

9.3 Reporting Procedures

Unanticipated Problems. For unanticipated problems, the County Counselor will contact and inform the study Co-PI’s (Dr. Riedy) immediately and will send by email or fax the unanticipated problem report to the Co-PI’s as soon as possible. The Co-PI’s will verify or clarify the information with the participant or participants’ family member. The Co-PI’s will notify the UW-IRB, the Oregon PH IRB, and the NIDCR Medical Monitor via telephone, email, or fax of the unanticipated problem form.
within 24 hours, and by a full written report to follow as promptly as possible. Furthermore, the Co-PI’s will also notify the NIDCR PO.

All unanticipated problems that are also serious adverse events (AE’s) will be followed until satisfactory resolution or until the Co-PI’s deem the event to be chronic or the patient to be stable.

The contact information for the UW-IRB staff assigned to this study, and the NIDCR PO and Medical Monitor are below.

**UW Human Subjects Division staff assigned to this study:**
Elizabeth Falsberg, PhD
Human Subjects Review Administrator Committee C
falsberg@u.washington.edu
206 543-0098 Ext 2921

**Oregon Public Health IRB Chair:**
David Holt, JD
971 673-1221

**NIDCR Program Official:**
Ruth Nowjack-Raymer, MPH, PhD
NowjackR@de45.nidr.nih.gov
301-594-5394

**NIDCR Medical Monitor:**
Holli Hamilton, MD
hamiltonho@nidcr.nih.gov
301-451-3852

### 9.3.1 Studies Conducted under NIDCR-Sponsored IND

Section 9.3.1 is not applicable to this study.

### 9.3.2 Regulatory Reporting for Studies Not Conducted under NIDCR-Sponsored IND

Section 9.3.2 is not applicable to this study.
9.3.3 Other Unanticipated Problems

See Section 9.3.3

9.3.4 Reporting of Pregnancy

Section 9.3.4 is not applicable to this study.

9.4 Duration of Follow-up of Subjects after Unanticipated Problem

After discovery of the unanticipated problem, the County Counselor will contact the subject within one week to ask about the status of the unanticipated problem and will continue to contact the participant periodically (every day to every week) depending on the nature of the unanticipated problem until the event resolves or is determined to be a chronic condition by a clinician. All follow-up contacts with participants in relation to an unanticipated problem will be recorded and included as part of that particular unanticipated problem.

9.5 Halting Rules

The CSOC will meet to monitor the progress of the trial on a timeline determined by NIDCR. In addition, the CSOC may decide to convene a meeting at any time in response to reports of unanticipated problems. One important function of the CSOC will be to determine if the trial should be stopped early. Although the study control and experimental protocol are classified as minimal risks and there are no expected adverse medical or health events that would result in halting the trial, there are circumstances where the CSOC may halt the trial. In this section we provide three objective criteria based on accrual and dropout rates and unanticipated problems which the CSOC may use in determining whether the trial should be stopped early.

9.5.1 Unanticipated Problems

Unanticipated problems will be closely monitored and reported as described above.

Unanticipated problems will be summarized and reported to the CSOC. The events will also be tabulated and comparisons will be made between the intervention and control groups to assess the potential that occurrence rates are related to the
intervention (or control) group. These results will be reported to the CSOC.

The CSOC will determine and advise NIDCR whether the trial should be halted due to unanticipated problems.

9.6 Safety Oversight

The County Counselor will function as the first level of safety oversight by their observation, contact, and inquiries into the health of the participant and ascertaining and completing the unanticipated problems form. The counselor will also be responsible for following up the unanticipated problems with the participant until the condition resolves or deemed chronic by a clinician. The Co-PI's are responsible for reviewing all unanticipated problems, confirming the information with the participants as needed, and carrying out the appropriate reporting to the UW-IRB, the Oregon PH IRB, the CSOC, and NIDCR. All unanticipated problems will be entered into a database and the study statistician will produce a summary report for CSOC meeting.

The main safety oversight will be under the direction of a CSOC, an independent group of experts that appointed by and advisory to NIDCR and the study investigators. The members of the CSOC serve in an individual capacity and provide their expertise and recommendations. The primary responsibilities of the CSOC are to 1) periodically review and evaluate the accumulated study data for participant safety, study conduct and progress, and, when appropriate, efficacy, and 2) make recommendations to NIDCR concerning the continuation, modification, or termination of the trial. This study will follow the NIH guidelines regarding the oversight provided by the CSOC.
10 CLINICAL (OR FIDELITY OF THE INTERVENTION) MONITORING

10.1 Fidelity Monitoring Plan

Our approach to monitoring the fidelity of the intervention is based on the framework by Bellg et al., (2004), Treatment Fidelity Workgroup of the NIH Behavior Change Consortium (BCC). Bellg et al., described treatment fidelity as “the methodological strategies used to monitor and enhance the reliability and validity of behavioral interventions” and “the methodological practices used to ensure that a research study reliably and validly tests a clinical intervention.”

The BCC treatment fidelity approach encompasses five areas within which fidelity can be addressed prior to the intervention (study design, training interventionists) to during the intervention (delivery, receipt, and enactment of treatment skills). This section describes the activities that will be undertaken in the Baby Smiles study within these five areas to enhance and monitor the fidelity of the intervention.

Study Design:

Bellg et al., described several strategies for treatment fidelity in the design of the study such as,

“establishing procedures to monitor and decrease the potential for contamination between active treatments or treatment and control, procedures to measure dose and intensity (e.g., length of intervention contact, number of contacts, and frequency of contacts), and procedures to address foreseeable set-backs in implementation (e.g., therapist dropout over the course of a multiyear study).”

Within the design of the Baby Smiles study, the goals and strategies that will be used to enhance fidelity are:

- ensure same treatment dose within conditions.
o Within each condition (prenatal MI, prenatal control, postpartum MI, postpartum control), a standardized protocol manual will be used to ensure that within each of these conditions the participant has the same number of contacts and approximate length of contacts. The **County Counselor** will take notes of each encounter within the standardized protocol as well as noting the length of the encounter for the tracking database.

- ensure equivalent dose across conditions.
  
o For both the prenatal and postpartum MI and control conditions there will be the same number of contacts per participant. Although the length of contact will be in a similar range across conditions (20-45 minutes) we anticipate that the length might differ on an individual basis. Because of this we will have the **County Counselor** record the length of contact with each participant in the tracking database.

- plan for implementation setbacks.
  
o The study will train at least two County Counselors per intervention county in order to account for potential interventionist dropout. Additionally, supervisors of the counselors will be asked to attend the training and will serve as a backup in the event that both counselors are unavailable to the study.

### Training of Interventionists:

Strategies for monitoring and improving the training of interventionists recommended by the Bellg et al., article include,

"standardizing training, measuring skill acquisition in providers, and having procedures in place to prevent drift in skills over time."

Within the interventionist training of the Baby Smiles study, the goals and strategies that will be used to enhance fidelity are:

- standardize training.
  
o A 2-day training session led by the Baby Smiles study team will be conducted with all the **County Counselors** and their supervisors within the four intervention
counties. In advance of the training the County Counselor will send responses to a questionnaire asking about previous experiences working with the population and training in MI. These responses will help us tailor the training session better to account for any counselor differences. The County Counselor will also receive materials in advance of the training with which to familiarize themselves. The training session will incorporate the use of the standardized protocols/manuals. One of the Co-PI’s (Dr. Phil Weinstein) will lead the MI component of the training session which will involve didactic materials, structured practice and role-playing, and mock intervention sessions. The training will be videotaped in the event of future training as well as a refresher for booster sessions.

- ensure provider skill acquisition.
  - The County Counselors will be trained to defined performance criteria and be “certified”. During the training the counselors will be asked to undertake role-playing exercises which will be scored according to a pre-established checklist. After the role-playing exercise the County Counselors will evaluate their performance and self-identify (along with the trainer and other participants) problem solving opportunities.

- minimize “drift” in provider skills.
  - In order to minimize the possibility of the County Counselors drifting from the standardized protocols several checks will be instituted such as audio taped encounters during the delivery of the intervention (audio tapes will be coded for fidelity), access to study staff through weekly study team meetings with self-evaluations of performance of delivery of interventions, review of written information in standardized protocols, and regular booster sessions via video conference (1x per month for first 3 months; every other month for the 4th-6th month; every 4 months for the remainder of the study).

- accommodate provider differences.
  - Differences in the experiences and backgrounds of the County Counselors will be taken into account for the training session as well as for subsequent booster sessions. We expect that most of the counselors will have had some training in MI as all Oregon WIC program personnel have undergone MI training.
Delivery of Intervention:

In this section, recommended strategies for monitoring and improving the delivery of the treatment to ensure that it is delivered in the way that it was intended include,

“control for provider differences, reduce differences within treatment, ensure adherence to treatment protocol, and minimize contamination between conditions.”

Within the delivery of Baby Smiles study, the goals and strategies that will be used to enhance fidelity are:

- control for provider differences.
  - It is reasonable to assume that participants may react differently to the County Counselors depending on their interpersonal characteristics (e.g., perceived warmth and credibility). We will preemptively control for provider differences through the selection of the County Counselors. The counselors will have experience working within the population (women on the Oregon Health Plan) as well as interpersonal characteristics deemed important (warm, approachable, credible). Additionally, we will assess (and control) for counselor’s interpersonal differences by asking participants to complete a brief questionnaire about their perceptions of the provider’s warmth and credibility. The questionnaire will be returned directly to the University of Washington. We will also monitor any participant complaints that arise from their interactions with the counselors. Lastly, we will do a qualitative interview at the end of the study for debriefing purposes and will include questions related to the interpersonal characteristics of the counselors.

- reduce differences within treatment.
  - All County Counselors will receive the standardized protocols/manual for the conditions. Most of the protocols are scripted so that the counselors will have less chance to deviate from the intention of the condition. All counselors will
have their sessions audio taped and transcribed, and 20% will be reviewed and coded for fidelity purposes. The first five sessions will be audio taped and reviewed by the Co-PI’s so that immediate feedback can be given. The audio tapes will be coded by trained fidelity coders. Coders will complete a “checklist” based on the scales below as each audio tape is reviewed, the checklists will list the critical unique elements of the intervention, providing a reminder and fostering adherence to the planned intervention.

Rather than developing and validating a unique scale, we will modify the Yale Adherence and Competence Scale (YACS) developed by Carroll and colleagues (2000) and incorporate elements of the MIA: STEP’s Motivational Interviewing Rating Feedback Worksheet. YACS is a 55-item scale that taps general and specific elements of therapies for drug use disorders. YACS subscales assess both adherence and competence using simple Likert scales. The first dimension assesses whether the behavior occurred and with what intensity; the second, if the behavior occurred is a skillfulness rating.

Each item is phrased, “To what degree did the counselor....”

The following items will be used/modified:

**MI Consistent Items**  MI style or spirit
- Fostering a collaborative relationship
- Provide statements of support (affirmations)
- Reinforcing motivation to change/encouraging change talk
- Develop discrepancy
- Use open-ended questions
- Reflective listening
- Recognize and explore resistance

**MI Inconsistent Items:**
- Unsolicited advice, directions, and feedback
- Direct confrontation
The following is a sample of the form of the subscales:

### Adherence

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td>A little</td>
<td>Somewhat</td>
<td>Considerably</td>
<td>Extensively</td>
</tr>
</tbody>
</table>

### Competence

| Very poor | Poor | Adequate | Very Good | Excellent |

- ensure adherence to treatment protocol.
  - As described previously, the County Counselors will be using standardized protocols/manuals to deliver the intervention. These protocols/manuals will provide prompts for delivering specific content within the condition. The counselors will also be recording notes in the protocols/manuals that will be sent to the University of Washington and reviewed periodically by the Co-PIs to determine if the counselors are adhering to the protocol. These reviews will be communicated to the County Counselors in order to maintain their adherence.
  - County Counselors will complete a “checklist” after each contact with a subject, the checklists will list the critical unique elements of the intervention, providing a reminder and fostering adherence to the planned intervention. The checklist will be a modified version of the MIA-STEP Motivational Interviewing Clinician Self-Assessment Report (MI style or spirit, open-ended questions, affirmations of strengths and change efforts, reflective statements, and fostering a collaborative atmosphere).
- minimize contamination between conditions.
Although the primary way to minimize contamination between conditions is to have sites randomized instead of individuals we are unable to include this strategy. We have developed alternative ways to minimize contamination such as using specific protocols/manuals for each condition that the County Counselor will follow, provide the counselors with the rationale as to why the conditions are separate and distinct, and audio tape the counselors for fidelity of the condition and provide feedback.

Receipt of Intervention:

This section and the following section (enactment of treatment skills) focus on the patient/participant rather than the provider. The processes for monitoring and improving the patient’s ability to understand and perform treatment-related skills include,

“ensure participant comprehension, ensure participant ability to use cognitive skills, and ensure participant ability to perform behavioral skills.”

Within the receipt of the Baby Smiles study, the goals and strategies that will be used to enhance fidelity are:

- ensure participant comprehension.
  - The County Counselors will use standardized protocols/manuals that have key places for summarizing/paraphrasing what the participants have been discussing to ensure that participants understand the information being provided in the conditions. Additionally, the written information that will be provided to the participants will be written at a grade level between 5th-7th grades.
- ensure participant ability to use cognitive and behavioral skills.
  - The County Counselors will use standardized (and structured) protocols/manuals that have key places for encouraging and reinforcing the participants to ask questions or make comments. These structured scripts will allow the counselors to model and engage with the participant to ensure the cognitive (problem solving, preparing for specific situations) and behavioral
(relaxation skills) skills are employed. Additionally, the follow-up contacts will allow the counselors to monitor participants’ ability to perform the skills outlined in the intervention.

**Enactment of Treatment Skills:**

The section refers to the established processes for monitoring and improving the patient’s ability to perform treatment-related skills in *applicable real-life settings*. This includes ensuring “participant use of cognitive and behavioral skills”.

Within the enactment of the treatment skills of the Baby Smiles study, the goals and strategies that will be used to enhance fidelity are:

- ensure participant use of cognitive and behavioral skills.
  - The **County Counselors** will use standardized protocols/manuals that have key places for encouraging and reinforcing the participants to choose specific interventions that “fit” their circumstances; they will be asked to discuss problems that may emerge and to problem solve solutions.
  - The **County Counselors** will use standardized (and structured) protocols/manuals that have key places for encouraging and reinforcing the participants to rehearse aspects of the intervention, e.g., what to say to a dentist when you are fearful.
  - Additionally, the follow-up contacts will allow the counselors to monitor participants’ use of the skills outlined in the intervention.
11 STATISTICAL CONSIDERATIONS

11.1 Study Hypotheses

11.1.1 Primary Hypotheses

1. Women who receive Brief MI during pregnancy (Prenatal MI) from trained County Counselors will have a greater frequency of utilization of dental care during pregnancy than women from the traditional health education materials condition (Prenatal Traditional Health Ed).

Null hypothesis: The frequency of utilization of dental care during pregnancy will be the same for the two interventions given during pregnancy.

Alternative hypothesis (superiority): The frequency of utilization of dental care during pregnancy will be different for the two interventions given during pregnancy.

2. Brief MI post-partum (Postpartum MI) will result in greater utilization of preventive dental care for children during the first 18 months of life than the traditional health education materials condition (Postpartum Traditional Health Ed).

Null hypothesis: The frequency of utilization of preventive dental care for children will be same for the two interventions given post-partum.

Alternative hypothesis (superiority): The frequency of utilization of preventive dental care for children will be different for the two interventions given post-partum.

3. Brief MI during pregnancy combined with Brief MI during post-partum (Prenatal MI + Postpartum MI) will result in greater utilization of preventive dental care for children during the first 18 months of life than Brief MI only during pregnancy (Prenatal Traditional Health Ed + Postpartum MI).
Null hypothesis: The frequency of utilization of preventive dental care for children will be same for the two groups.

Alternative hypothesis (superiority): The frequency of utilization of preventive dental care for children will be different for the two interventions given post-partum.

11.1.2 Secondary Hypotheses

1. The number of preventive home oral health practices taken by mothers to prevent caries in their young children at 18 months post-partum will be higher among mothers who receive Brief MI as compared to mothers who receive traditional health education materials.

2. The Brief MI as compared to the traditional health education materials will result in a greater percentage of mothers classified by the Readiness Ladder as in the action stage versus precontemplation and contemplation stages at 3 and 18 months post-partum.

3. A women’s readiness to change will mediate the effects of the Brief MI intervention on preventive dental utilization during pregnancy and utilization of preventive dental care for the child during the first 18 months of life.

11.2 Sample Size Considerations

The proposed sample size is to enroll a total of 400 women into the study, with 80 to 120 women enrolled within each of the four study counties. Randomization will be stratified by county and counselor. Women will be enrolled into one of four groups with the frequencies as shown below.
<table>
<thead>
<tr>
<th>Pregnancy (Prenatal) MI</th>
<th>Child (Postpartum) MI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Yes</td>
<td>Group 1</td>
</tr>
<tr>
<td></td>
<td>(Prenatal MI – Postpartum MI)</td>
</tr>
<tr>
<td></td>
<td>N=148</td>
</tr>
<tr>
<td>No</td>
<td>Group 3</td>
</tr>
<tr>
<td></td>
<td>(Prenatal Traditional Health Ed – Postpartum MI)</td>
</tr>
<tr>
<td></td>
<td>N=148</td>
</tr>
</tbody>
</table>

The goal of the sample size calculations is to ensure high statistical power to demonstrate a higher utilization of dental care during pregnancy and a higher utilization of preventive dental care for children during the first 18 months of life for the groups receiving MI versus traditional health education, as well as to have sufficient statistical power to demonstrate that the group receiving Postpartum MI in combination with Prenatal MI will have higher utilization of preventive dental care for children during the first 18 months of life than the group receiving Postpartum MI without MI during pregnancy.

Three a priori group contrasts of key interest will be used to test the primary hypotheses:

- Primary hypothesis 1. Compare the two groups receiving MI during pregnancy (Groups 1 & 2) to the two groups receiving traditional health education during pregnancy (Group 3 & 4) to demonstrate that MI will result in a greater frequency of utilization of dental care during pregnancy.

- Primary hypothesis 2. Compare the two groups receiving MI post-partum (Groups 1 & 3) to the two groups receiving traditional health education post-partum (Groups 2 & 4) to demonstrate that MI will result in a greater frequency of utilization of preventive dental care for children during the first 18 months of life.
Primary hypothesis 3. Compare the group receiving MI during pregnancy and post-partum (Group 1) to the group receiving MI only post-partum (Group 3) to demonstrate that combination of the MI during pregnancy and post-partum will result in a greater frequency of preventive dental care for children during the first 18 months of life.

These three contrasts are sufficient to demonstrate the effect of MI during pregnancy on mothers’ utilization during pregnancy, the effect of MI post-partum on child utilization, and the effect of the combination of MI during pregnancy and post-partum on child utilization. A significance level of 0.016 is used in the sample size and power calculations for the primary hypotheses to take into account the three comparisons being performed.

The study will also provide some evidence for the effect of MI during pregnancy without MI post-partum on child utilization. However, the study is not powered to demonstrate this effect, which will likely be modest in the absence of intervention post-partum. Grembowski et al (2008) showed a modest increase in child dental utilization due to a regular source of dental for the mother. In a very unlikely and unexpected scenario that an increase in child utilization is due solely to women receiving MI during pregnancy this effect would be demonstrated by the comparisons for Primary hypotheses 2 and 3 (e.g., finding no overall effect for MI post-partum on child utilization, but increased child utilization for the combination of MI during pregnancy and post-partum).

The analysis strategy for the primary hypotheses will involve intent-to-treat analyses, where women and their children will be compared accordingly to their randomly assigned intervention regardless of whether they received the intervention. The only exception to the intent-to-treat principle is that the analysis for child utilization of preventive dental care will be limited to only live-born children (e.g., miscarriages and stillborns will be excluded).

Primary hypothesis 1. To test primary hypothesis 1 the percentage of women with dental care utilization during pregnancy (and up to two months post-partum) will be compared between the two groups receiving MI during pregnancy (Groups 1 & 2) and the two groups receiving traditional health education materials during pregnancy (Groups 3 & 4) using logistic regression.

We expect the percentage of dental care utilization by women in the traditional health education groups to be low, 15 to 25% at most, based on Milgrom et al (2008) which found that only 8.8%
of pregnant women served by Medicaid in Oregon received dental care. We expect the use of dental care during pregnancy to be 50 to 60% for women in the Brief MI intervention, based on Milgrom et al (2008) in which 56% of eligible pregnant women in the community-based intervention to provide a dental home received dental care.

Given we will be able to obtain the dental utilization data from the Medicaid database on all subjects, except those that explicitly refused further participation in the study, we expect the attrition rate to be 10% or less. With the proposed sample size, as shown in Table 1, the statistical power will be high to demonstrate a greater frequency of utilization of dental care during pregnancy among women in the Prenatal MI groups than women in the traditional health education materials groups. We have shown the power for lower rates of utilization for the Prenatal MI groups than expected to demonstrate that the power is still adequate if the brief MI intervention during pregnancy is less effective than anticipated.

Table 1. Power to demonstrate an intervention effect of brief MI during pregnancy (Prenatal MI) on utilization of dental care during pregnancy based on a two-sided chi-square test at a 0.016 significance level.¹

<table>
<thead>
<tr>
<th>Frequency of dental utilization in mothers</th>
<th>Power</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prenatal Traditional Health Ed²</td>
<td>Prenatal MI²</td>
</tr>
<tr>
<td>15%</td>
<td>35%</td>
</tr>
<tr>
<td></td>
<td>40%</td>
</tr>
<tr>
<td></td>
<td>45%</td>
</tr>
<tr>
<td>20%</td>
<td>40%</td>
</tr>
<tr>
<td></td>
<td>45%</td>
</tr>
<tr>
<td></td>
<td>50%</td>
</tr>
<tr>
<td>25%</td>
<td>45%</td>
</tr>
<tr>
<td></td>
<td>50%</td>
</tr>
<tr>
<td></td>
<td>55%</td>
</tr>
</tbody>
</table>
Primary hypothesis 2. To test primary hypothesis 2 the percentage of children with preventive dental care during the first 18 months of life will be compared between the two the groups receiving Postpartum MI (Groups 1 & 3) and the two groups receiving the Postpartum traditional health education materials (Groups 2 & 4) using logistic regression. In addition to stratifying on county, the logistic regression analysis will be stratified based on the intervention the women were randomly assigned to receive during pregnancy.

Based on the National Survey of Children’s Health (2003), the use of preventive dental care services by children during the first 18 months is very low (~10%). In our study of the Washington’s State Access to Baby and Child Dentistry program (ABCD) only 12% of Medicaid-enrolled children had any utilization of dental care during 24 and 48 months of age and only 2.4% of children had any dental utilization during 12 to 24 months of age (Grembowski et al, 2000; Milgrom et al, 1997). We have assumed somewhat higher rates of utilization, 5% to 15%, for the power calculations given mothers who participate in the study may be more likely to seek dental care for their child. Based a study by Grembowski et al (2008) of low-income families covered by Medicaid in Washington State, which showed that child dental care utilization is higher (5% to 10% higher) when mother’s have a regular source of dental care, we expect a modest increase in child utilization during the first 18 months of life, 15% to 25%, due to MI given during pregnancy in the absence of MI intervention post-partum. Based on the ABCD study which found that the ABCD program increased child utilization by 3.5 times or greater and a preliminary study by Grembowski et al, (unpublished data, 2007), we expect the utilization of the preventive dental care services by children of mothers receiving MI only post-partum to be 20% to 40% and for mothers receiving the MI both during pregnancy and post-partum to be 40 to 60%.

Given we will be able to obtain the dental utilization data from the Medicaid database on all subjects, except those that explicitly refused further participation in the study, we expect the
attrition rate to be 10% or less. With the proposed sample size, as shown in Table 2, the study has high statistical power to demonstrate a greater frequency of utilization of preventive dental care for children during the first 18 months of life for the groups receiving MI post-partum as compared the groups receiving traditional health education post-partum.

Table 2. Power to demonstrate effect of brief MI post-partum (Postpartum MI) on utilization of preventive dental care for children during the first 18 months of life based on two-sided chi-square test at a 0.016 significance level.¹

<table>
<thead>
<tr>
<th>Frequency of preventive dental care in children</th>
<th>Power</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prenatal</td>
<td></td>
</tr>
<tr>
<td>Traditional Health Ed + Postpartum Traditional Health Ed (Group 2)</td>
<td></td>
</tr>
<tr>
<td>Prenatal MI + Postpartum</td>
<td></td>
</tr>
<tr>
<td>Traditional</td>
<td></td>
</tr>
<tr>
<td>Prepartum MI + Postpartum MI (Group 3)</td>
<td></td>
</tr>
<tr>
<td>Group 3&amp;4 versus Group 1&amp;2</td>
<td></td>
</tr>
<tr>
<td>Prepartum MI + Postpartum MI (Group 1)</td>
<td></td>
</tr>
<tr>
<td>Prepartal Traditional Health Ed</td>
<td></td>
</tr>
<tr>
<td>Prepartal MI + Postpartum MI (Group 1)</td>
<td></td>
</tr>
<tr>
<td>Prepartal MI + Postpartum MI (Group 1)</td>
<td></td>
</tr>
</tbody>
</table>


Primary hypothesis 3. To test primary hypothesis 3 the percentage of children with preventive dental care during the first 18 months of life will be compared between the two the groups receiving Postpartum MI (Groups 1 & 3) using logistic regression. The same assumptions on the dental utilization of preventive dental for children during the first 18 months life are assumed for the sample size calculations for hypotheses 2 and 3.
With the proposed sample size, as shown in Table 3, the study has sufficient power to demonstrate a greater frequency of utilization of preventive dental care for children during the first 18 months of life for the group receiving MI both during pregnancy and post-partum (Group 1) as compared to the group receiving MI only post-partum (Group 3).

Table 3. Power to demonstrate effect of brief MI during pregnancy in combination with brief MI post-partum (Prenatal MI + Postpartum MI) on utilization of preventive dental care for children during the first 18 months of life based on two-sided chi-square test at a 0.016 significance level.¹

<table>
<thead>
<tr>
<th>Frequency of preventive dental care in children</th>
<th>Power</th>
</tr>
</thead>
<tbody>
<tr>
<td>PrenatalTraditional Health Ed + Postpartum MI (Group 3)</td>
<td>Prenatal MI + Postpartum MI (Group 1)</td>
</tr>
<tr>
<td>20%</td>
<td>40%</td>
</tr>
<tr>
<td>30%</td>
<td>50%</td>
</tr>
<tr>
<td>40%</td>
<td>60%</td>
</tr>
</tbody>
</table>


11.3 Planned Interim Analysis

No formal interim analysis is planned for stopping the study early. By the time potentially sufficient outcome data is available on child utilization of preventive dental care during the first 18 months of life (e.g., half the primary outcome data on child utilization would be available by Y4 6mo; see Figure 4.2.2) all women enrolled in the study would have completed the prenatal-focused stage of the intervention and nearly all women would be beyond the postpartum-focused stage of intervention (3 months post-partum + six weeks).
11.3.1 Safety Review
Section 11.3.1 is not applicable for this study.

11.3.2 Efficacy Review
Section 11.3.2 is not applicable for this study.

11.4 Final Analysis Plan

The analysis strategy for the primary hypotheses will involve intent-to-treat analyses, where women and their children will be compared accordingly to their randomly assigned intervention regardless of whether they received the intervention. The only exception to the intent-to-treat principle is that the analysis for child utilization of preventive dental care will be limited to only live-born children (e.g., miscarriages and stillborns will be excluded). For gathering information on birth outcome, County Counselors will be contacting participants regarding birth outcomes as miscarriages will not be on the birth record.

Briefly, mother and child dental utilization, oral health impact, oral health knowledge, oral hygiene and dietary practices, readiness, perinatal depression, perceived stress, dental anxiety, and fatalism will be compared according to the three a priori group contrasts described in Sample Size Considerations using logistic and linear regression methods. Separate regression analyses will be done for each contrast, and a significance level of 0.016 will be used for all comparisons.

A preliminary step in the analysis will be to check if the women in the four groups are comparable on baseline values of prior dental utilization and important predictors of dental utilization (e.g. Readiness Ladder status, oral health quality of life). If an imbalance is found between the groups, additional covariates will be included in the regression analyses described below to adjust the intervention comparisons for baseline differences. The primary independent variable in the regression analyses will be an indicator variable for intervention group, and in addition, indicator variables for county and counselor will be included in all regression models to account for the stratification of the randomization by county and counselor (See Randomization Procedures). In addition, if necessary, additional indicator variables for different recruitment
locations (e.g., public health departments/WIC settings) within a county or counselor will be included in all regressions to account for potential correlation by recruitment location. In general, for most of the counties and counselors recruitment will occur from one location.

Descriptive summaries will be produced for all the primary outcomes (mother and child dental utilization) by intervention group averaged over the four study counties, as well as, by county to assess the similarity of the observed intervention effects across the different counties. Formal testing for differences in the intervention effect among counties is possible by testing for interactions between county and intervention group in the regression analyses described below. However, we do not expect the intervention effects to differ vastly among the counties, and the sample size has not been selected to test for such county differences.

**Primary hypothesis 1.** Logistic regression analysis will be used to test primary hypothesis 1 that more women in the Prenatal MI intervention (Groups 1 & 2) will have dental care utilization during pregnancy (and to two months post-partum) than women in the traditional health education materials intervention (Groups 3 & 4). The outcome variable will be a binary variable indicating whether or not the woman used any (1 or more) dental services during pregnancy, where use of dental care services is determined from the Medicaid database. The primary independent variable will be an indicator variable for intervention group (Group 1 or 2 versus Group 3 or 4) and, in addition, indicator variables for county and counselor will be included in the logistic regression to account for the stratified randomization by county and counselor.

Additional analyses will also compare the intervention groups for other types (non-preventive) of dental care utilization.

**Primary hypothesis 2.** Logistic regression analysis will be used to test primary hypothesis 2 that more children of mothers in the Postpartum MI intervention (Groups 1 & 3) will have preventive dental care utilization during the first 18 months of life than children of women in the Postpartum Traditional health education materials intervention (Groups 2 & 4). The outcome variable will be a binary variable indicating whether or not the child used any (1 or more) preventive dental services during the first 18 months of life, where use of dental care services is determined from the Medicaid database. The primary independent variable will be an indicator variable for intervention group (Group 1 or 3 versus Group 2 or 4). Indicator variables for county and
counselor will be included in the logistic regression to account for the stratified randomization by county and counselor, and an indicator variable for intervention group during pregnancy will be included in the logistic regression to stratify the analysis based on the intervention during pregnancy. Additional logistic regression analyses will compare rates of preventive dental care utilization during the first 12 months of life, since the American Academy of Pediatric Dentistry (AAPD) recommends that children be seen by the dentist by the first 12 months of life.

**Primary hypothesis 3.** Logistic regression analysis will be used to test primary hypothesis 3 that more children of mothers receiving brief MI both during pregnancy and post-partum (Group 1) will have preventive dental care utilization during the first 18 months of life than children of women receiving brief MI only post-partum (Group 3). The outcome variable will be a binary variable indicating whether or not the child used any (1 or more) preventive dental services during the first 18 months of life, where use of dental care services is determined from the Medicaid database. The primary independent variable will be an indicator variable for intervention group (Group 1 versus Group 3), and indicator variables for county and counselor will be included in the logistic regression to account for the stratified randomization by county and counselor. Additional logistic regression analyses will compare rates of preventive dental care utilization during the first 12 months of life, since the AAPD recommends that children be seen by the dentist by the first 12 months of life.

**Secondary Analyses**

The data from the baseline questionnaire during pregnancy, and the questionnaires at 3, 9 and 18 months post-partum will be used for several purposes: 1) As described in the analyses of the primary hypotheses the baseline questionnaire will be used to assess the comparability of the two interventions on predictors of dental utilization at baseline (e.g. Readiness Ladder status, oral health quality of life). 2) Administering questionnaires at 3 and 9 month post-partum will help maintain contact with the mothers and ensure higher retention rate for the final follow-up, and; 3) All four questionnaires will be used to describe and assess how the mother’s readiness to change and other factors, such as depression, oral health knowledge, oral health quality of life, oral hygiene and dietary practices, and dental anxiety, as well as changes in these variables over the study period, mediate or moderate the effect of the Brief MI intervention.
It is hypothesized that the brief MI as compared to the traditional health education materials will result in a greater number of home oral health practices taken by the mother to prevent caries in their young children during the first 18 months of life. The total number of home oral health practices by the mother as reported on the questionnaire at 18 months post-partum will be compared between mothers in the Postpartum MI intervention (Groups 1 & 3) and mothers in the Postpartum Traditional health education materials intervention (Groups 2 & 4) using linear regression analysis.

The brief MI as compared to the traditional health education materials will result in a greater percentage of mothers classified by the Readiness Ladder as in the action stage versus precontemplation and contemplation stages; a greater increase of oral health knowledge and self-efficacy; and lower oral health fatalism at 3 and 18 months post-partum. Logistic and linear regression analysis, similar to the analytical approach for the primary hypotheses, will be used to test the secondary hypotheses concerning readiness for change (Readiness Ladder), oral health knowledge (KBU, KCOH), self-efficacy (OHSE), and fatalism (OHF) based on the questionnaire at 3 and 18 months post-partum. Additional logistic and linear analyses will assess what subject factors (e.g., socio-demographic factors, measures of readiness to change, oral health knowledge, self-efficacy, and fatalism) from the initial questionnaire during pregnancy are associated with the mother’s and child’s use of preventive dental services and the number of oral hygiene and appropriate dietary activities. Binary outcomes in the logistic regression analyses will include whether or not the mother had 1 (or more) dental services during pregnancy, and whether or not the child had 1 (or more) preventive dental services by the 18 months of age. A continuous outcome in the linear regression analyses will be the average (self-reported) number of times the parent tried to clean the child’s teeth in the past week at 18 months of age.

It hypothesized that outcomes will be mediated by a women’s readiness to change. A mediator is a variable that is responsible for all or part of the effect of an intervention on an outcome. To be a mediator, a variable must change during the intervention, be associated with the intervention and have an effect on the outcome. We will test whether changes in readiness to change over the course of the intervention will mediate the effects of the Brief MI intervention on
the outcome measures for the mother at 3 months post-partum and for the child by 18 months of age. First, the analyses for the primary hypotheses will be used to examine whether there is an effect of the Brief MI intervention on mother’s outcomes at 3 months post-partum and child outcomes by 18 months of age. Second, to demonstrate the association between the intervention and readiness to change, we will construct regression models with readiness to change as the dependent variable (e.g., change between baseline and 3 months post-partum for the mother’s outcomes, and change between and/or 3 months post-partum and 9 or 18 post-partum for the child’s outcome) and intervention and the baseline value of readiness to change as independent variables. Third, to demonstrate the association between readiness to change and the outcome after adjusting for the intervention and to demonstrate the reduction of the intervention effect on the outcome after adjusting for readiness to change, we will construct regression models with both treatment and readiness to change as independent variables and the outcome measure as the dependent variable.

To formally test the mediation effect in the third step, we will use a version of the Sobel test (Sobel 1982), which tests whether the indirect effect of intervention on the outcome through the mediator (defined as the product of the intervention to mediator path and the mediator to outcome path) is significantly different from zero. The mediation effect is referred to as the indirect effect of intervention because it reflects the intervention effect on the outcome through the mediating variable (MacKinnon, 2000). We will use the bootstrap method of Preacher and Hayes (2004) to estimate the indirect effect and bias-corrected 95% confidence interval (CI) for each individual mediator and for all the mediators as a group, based on 1,000 bootstrap samples using a Statistical Package for the Social Sciences (SPSS®; SPSS Inc., Chicago, Illinois) macro (http://www.comm.ohio-state.edu/ahayes/SPSS%20programs/indirect.htm). This methodology has been recommended as superior to a normal theory approach because it does not require that the sampling distribution of the indirect effect be normal (Shrout and Bolger, 2002; Preacher and Hayes 2004).

Moderators of intervention outcomes are typically baseline characteristics that interact with the intervention to affect outcomes. Logistic and linear regression analyses will be performed to identify if baseline variables, such as depression, oral health knowledge, and dental anxiety, health fatalism, are predictive of mother’s outcomes and child’s outcomes, and whether any of...
these variables moderate the intervention effect. The independent variable in these analyses will include an indicator for the intervention group contrast of interest, the baseline variable, and an interaction between the baseline variable and intervention group.

**Missing data**

An attempt to minimize attrition (and missing data) has been described in the section on retention and attrition. We expect to have an 85% retention rate based on Weinstein et al., 2006. We will have higher rates of follow-up on dental utilization, given that we will be able to obtain utilization data from the Medicaid database on all subjects, except those who explicitly refuse further participation in the study. In the case of non-ignorable non-response, a method based on augmented inverse probability of censoring weighted (IPCW) estimating equations will be used to perform a sensitivity analysis that examines how the estimated intervention effect on the primary outcome measure changes over a range of plausible values for the non-response mechanism (Rotnitzky et al., 2001).
12 SOURCE DOCUMENTS AND ACCESS TO SOURCE DATA/DOCUMENTS

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

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

- study forms which are part of the Case Report Form (CRF) (e.g., eligibility criteria, questionnaires, counseling protocol notes, fidelity monitoring checklists and ratings, unanticipated problem report) (paper-based)
- tracking database (electronic)
- recorded audio tapes of counseling sessions (electronic; audio tapes are kept for only 8 weeks; transcriptions of tapes will not have identifiable information)
- memoranda (paper-based)
- DMAP Medicaid claims datasets (electronic)
13 QUALITY CONTROL AND QUALITY ASSURANCE

13.1 Definitions:

13.1.1 Quality Assurance (QA)

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

13.1.2 Quality Control (QC)

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

13.2 MI Intervention and Study Questionnaires

13.2.1 Quality Assurance Procedures

The County Counselors, who will implement the MI intervention and conduct the questionnaires, will attend a 2-day training program on the conduct of the study protocol (including the interventions) and logistics. As part of the training, the counselors will practice (via role playing) with the trainers to ensure that they meet a minimum level of competence. Fidelity of the counselors competence will be assessed periodically throughout the study (Refer to Section 10 Clinical (or Fidelity of the Intervention) Monitoring).

13.2.2 Quality Control Procedures

All of the MI intervention counseling sessions will be audio recorded in digital media and stored in secured study computers. Audio tapes will be transcribed within 8 weeks of the session and then destroyed. A portion (20%) of the MI intervention counseling sessions will be coded. At the beginning of the study, the Co-PI's will review the first five counseling sessions to ensure fidelity of the sessions and accuracy of data recording. Counselors will be provided with feedback on their performance and conduct including but not limited to these specific areas:
• Overall spirit of MI
• Recognizing change talk and resistance
• Eliciting and strengthening change talk
• Rolling with resistance
• Developing a change plan
• Consolidating commitment
• Transition and blending

**County Counselors** with a session with less than acceptable quality will receive a private booster training session focused on problematic areas. This QC activity will take place monthly until the first five sessions have been completed after implementation of the study intervention. This will ensure that any weaknesses in study protocol will be addressed early. Subsequently, this QC activity will take place quarterly.

All data entry of study forms and questionnaires will be the responsibility of the S&DCC at the UW. **County Counselors** will make a copy of the forms/questionnaires and send the copy to the UW for data entry. The original forms/questionnaires will remain at the local site in secured/locked file cabinets. Each form and questionnaire will be entered with double-entry. Any field that is unclear will be clarified with the counselor who completed the document. Quarterly, all study forms and questionnaires collected and entered into the database will be merged and cross checked for inconsistencies and range and assessed for missing data. Any inconsistencies, outliers, or missing data observed will be compared to the paper document and appropriate corrective actions carried out.
13.3 Medicaid Dental Utilization Data Obtained from Oregon Division of Medical Assistance Programs (DMAP)

13.3.1 Quality Assurance

The study will request the complete set of Medicaid dental utilization data by CDT (Current Dental Terminology) code for study participants from the Oregon DMAP, part of DHHS. We will be seeking approval from DMAP for these data. DMAP will also provide a sub-dataset which includes only study participants. DMAP will merge the list of study participants (with their study ID number) with the Medicaid Claims Data using the Medicaid ID number (mother’s and child’s number) then strip the sub-dataset of identifier information leaving only the study ID number, and the dental utilization data by CDT coded.

13.3.2 Quality Control

The datasets that will be provided to the study team by DMAP will be reviewed, cleaned, and checked for consistency and range by staff of the Statistical and Data Coordinating Center (S&DCC).
14 ETHICS/PROTECTION OF HUMAN SUBJECTS

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

14.2 Institutional Review Board
The intervention study, study protocol, and accompanying materials (recruitment, consent, and questionnaires) will be reviewed by the University of Washington Institutional Review Board (IRB) (FWA#: FWA00006878) prior to implementing the study and the Oregon State Institutional Review Board. The UW-IRB will serve as the parent IRB to the four intervention counties. Each intervention county will have Federalwide Assurance approval. All amendments/modifications to the study protocol and accompanying materials will be approved before they are implemented.

14.3 Informed Consent Process
From the UW Human Subject Manual:

“Human subjects asked to contribute their time and effort to research should consent to do so freely. The consent should be given only after the subject understands what he or she is consenting to, and any risks that may be involved. Subjects should be assured that there will be no penalties for declining to participate, and that they are free to withdraw from the research at any time after they have given their initial consent. Federal regulations state this more formally:

‘An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the
representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.’

The requirement for informed consent is ordinarily fulfilled by telling the subject, either orally or in writing,

1. the general nature and purpose of the research,

2. the procedures in which the subject is being asked to participate, and the amount of time and effort likely to be required,

3. that the subject’s privacy will be respected,

4. that participation is voluntary and the subject is free to withdraw from participation at any time and free to decline to participate in any part of the procedures to which the subject may object, and

5. whom the subject may contact to find out more about the study.

Federal regulations require that, in most cases, whenever there is more than minimal risk, consent is to be documented by a signed and dated consent form that has been approved by a Human Subjects Review Committee. A copy must be provided to the participant or the participant’s legal representative.”

Informed consent is a process that is initiated prior to the individual’s agreeing to participate in the study and continuing throughout the individual’s study participation. Discussion of risks and possible benefits of this intervention will be provided to the women. Consent forms describing in detail the study intervention, study procedures, and risks are given to the woman and written documentation of informed consent is required prior to starting the intervention.

The study consent form will be IRB-approved and the recruited pregnant women will be asked to read and review the document. One consent form including both stages (pregnancy and motherhood) will be used. Upon reviewing the document, the County Counselor will explain the research study to the women and answer any questions that may arise. The women will sign the informed consent form prior to any procedures being done specifically for the study. The women will have the opportunity to discuss the study with their family or think about it prior to agreeing to participate. The women may withdraw consent at any time throughout the course of the study. A signed and dated copy of the informed consent document will be given to the women for their records. The rights and welfare of the women will be protected by emphasizing
to them that the quality of their care will not be adversely affected if they decline to participate in this study.

### 14.4 Exclusion of Women, Minorities, and Children (Special Populations)

The target population for the intervention will be pregnant and postpartum women and their children. This study will also include pregnant minors (15-17 years old). The Oregon State Institutional Review Board determined that “since Oregon law permits minors ages 15-17 to consent to medical treatment without parental permission, and since the research involves procedures for which a pregnant minor can currently give consent outside the context of the research, these individuals do not meet the definition of children as defined at 45 CFR 46.402(a). Federal regulations 45 CFR 46, Subpart D would therefore not apply to this research and parent permission is not a consideration. Minors may provide their own informed consent for this research.” This study will be limited to English speakers as they make up the largest percentage of county residents. We also determined in our planning that many Spanish-speaking women on OHP did not have full (medical and dental) coverage.

Children of previously enrolled pregnant women will be included in the study insofar that only their dental utilization will be assessed.

### 14.5 Subject Confidentiality

Subject confidentiality is strictly held in trust by the participating investigators, their staff, representatives for the University of Washington Institutional Review Board, the Oregon Public Health Institutional Review Board, and the representatives of the study sponsor (NIDCR). This confidentiality is extended to cover mental status in addition to the clinical information relating to participating subjects.

The study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.
The study monitor or other authorized representatives of the sponsor may inspect all documents and records required to be maintained by the investigator. The county intervention site will permit access to such records.

14.6 Study Discontinuation

In the event that the study is discontinued, the current study enrollees will be advised that the research period has ended, and that they may contact their county health department for continuing health counseling.

14.7 Future Use of Stored Specimens

Section 14.7 is not applicable to this study.
15 DATA HANDLING AND RECORD KEEPING

15.1 Data Management Responsibilities

Record keeping:
All original completed forms and questionnaires will be kept at the local site in secured/locked file cabinets. All audio recordings of counseling sessions will also be stored in secured/locked file cabinets at all times when not being used/reviewed. All electronic information including the password protected “Participant Tracking Database” will be stored in secured password-protected computers.

The contact/tracking form and ACCESS tracking database will contain the participant’s address, phone number, Medicaid ID# (as well as child’s when born), and additional contact names and phone numbers to facilitate contact with the participant and minimize lost to moving during the follow-up period. This information is stored as mentioned above and only available for use by County Counselor to enhance participant retention and adherence to the follow-up protocol. It may also be used to facilitate tracking and follow-up of unanticipated problems.

All data, forms, questionnaires, recording collected will be completely confidential and will not be shared with anyone except study personnel with defined needs to access the information.

The County Counselors and the Data Manager have complete access to the identifiable information as this is necessary to complete the assigned tasks in follow-up, retention, and adherence to protocol by participants. The Clinical Scientific Oversight Committee (CSOC), NIDCR Program Official (PO), University of Washington Institutional Review Board (UW IRB), Oregon Public Health Institutional Review Board (Oregon PH IRB) and Co-PI’s may request for identifiable information when necessary, such as cases of unanticipated problems, death, or other circumstances. These requests must be approved by the CSOC and the NIDCR PO. The remaining UW study team will not have access to identifiable information unless deemed necessary by the CSOC and NIDCR PO for specific reasons.

Data Handling:
The Medicaid claims data provided by Oregon Division of Medical Assistance Programs (DMAP) to the S&DCC will also be stored in secured computers.
The **County Counselors** will have the overall responsibility of ensuring the accuracy, completeness and legibility of the forms and questionnaires used in the study protocol. Counselors are also responsible for timely delivery of a copy of all data forms and questionnaires to the UW. All study forms and questionnaires (except the tracking database and consent form) will contain only the participant study ID number and no other identifiable information such as name, address or Medicaid number. Prior to sending any copy data forms or questionnaires to the UW, the **County Counselor** must ensure that there are no identifiable information (names, address, Medicaid ID number, etc.) on the documents. Any identifiable information on the copies must be white-out.

The **S&DCC** staff will be responsible for double-data entry of the data received from the **County Counselors** into the database and validate the information entered. Any errors, missing field, or outliers noted will be verified with the **County Counselor** and the original study forms for corrective actions. All errors found from periodic checks will be summarized in a data cleaning report and used in data quality assurance assessment and corrective actions. Error rates will be documented for **CSOC** reporting. The **S&DCC** will be responsible for data management, quality review, analyses, and reporting of the study data.

The database will be stored on secured password protected computers and will only be made available to study staff or to those directed by the **CSOC** and **NIDCR PO** during the study.
15.2 Data Capture Methods

Data for this study are captured using forms, questionnaires, and audio recording. Additional source data is dental utilization by CDT code from the state of Oregon Medicaid claims data provided by DMAP. No clinical or laboratory data will be collected from the participants.

As described above, all data forms, questionnaires will be entered into database stored in a secure password protected computer at the University of Washington, School of Dentistry. DMAP-provided datasets will also be stored in a secure password protected computer at the same location. Recorded audio will be stored in secured/locked cabinets in one of the Co-PI’s office.

15.3 Types of Data

Data for this study will include: (1) Medicaid CDT code utilization data; and (2) study questionnaires. Additionally, audio tapes will be used for fidelity monitoring. Form revisions should be minimal, however, should they occur, changes will be submitted to the study team for updating and dissemination to County Counselors.

15.4 Timing/Reports

Enrollment and study questionnaire data will be reviewed on a continual basis for accuracy and completeness. A monthly review will be done for the enrollment and follow-up data; a quarterly review will be done for the study questionnaire data. The County Counselors will review the questionnaires after the participants have completed them, and the study staff and S&DCC will do a final review after the documents have been transmitted from the County Counselors. An annual report (or as requested by the CSOC or NIDCR PO) will also be generated for sharing progress of the study.

Medicaid dental utilization (claims) data will be cleaned and checked by the S&DCC after the datasets are received from DMAP. The data from DMAP will be requested three times; once for the mother’s data and twice for the child’s data. The mother’s data will be requested at the end of the follow-up period (i.e., three months after the birth of the last enrolled participant). The child’s data will be requested twice, 12 months after the birth of the last enrolled participant and 18 months after the birth of the last enrolled participant.
15.5 Study Records Retention

Study documents should be retained for 30 years after the completion of the study. These documents may be retained for a longer period, however, if required by local regulations or determined necessary by the CSOC, NIDCR PO, Oregon PH IRB, or UW-IRB. No records will be destroyed without the written approval of the NIDCR.

From the University of Washington Record Retention Schedule:

**Clinical Trials Phase I-IV Research Data -- Investigator:** Research data and documentation gathered or created in the course of Phases I, II, III, or IV of a clinical trial sponsored by an agency outside the University or by the University, which is reviewed by the full IRB (Institutional Review Board). May include case history records, case reports, study protocol and amendments, patient care data, objectives and purpose of the study, selection criteria, clinical procedures, FDA forms, serious adverse events reports, study design and other documentation relating to study protocols. Does not include material also maintained in the official patient medical record.

*Official Copy:* Principal Investigator  
*Retention:* 30 years after close of study  
*Disposition Method:* Shred

15.6 Protocol Deviations

A protocol deviation is any noncompliance with the study protocol, Good Clinical Practice (GCP), or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site (i.e., intervention county) staff (e.g., County Counselor). As a result of deviations, corrective actions are to be developed by the Co-PI’s and the CSOC and implemented promptly.

It is the responsibility of the site (i.e., intervention county) to use continuous vigilance to identify and report deviations within 5 working days of identification of the protocol deviation. All deviations must be promptly reported to the Co-PI’s (Dr. Riedy or Dr. Weinstein) who will investigate the event and will inform the NIDCR PO and CSOC. The Co-PI’s will also complete the standardized UW-IRB, Oregon PH IRB, and NIDCR Protocol Deviation Forms for the event.
To reduce the possibility of protocol deviations, **Klamath County** (subcontract) staff with oversight by the S&GCC staff will be responsible for conducting “assistance and monitoring” visits with the sites (i.e., intervention counties). During these visits the staff member will review the data storage practices, examine the signed consent forms, and study logs.
16 PUBLICATION POLICY

Following completion of the study, the investigators are expected to publish the results of this research in a scientific journal. The International Committee of Medical Journal Editors (ICMJE) member journals have adopted a trials-registration policy as a condition for publication. This policy requires that all clinical trials be registered in a public trials registry such as ClinicalTrials.gov*, which is sponsored by the National Library of Medicine. Other biomedical journals are considering adopting similar policies. It is the responsibility of NIDCR or its grantee institution to register this trial in an acceptable registry. In addition, NIH Public Access Policy requires the principal investigator to submit journal articles that arise from NIH funds to the digital archive PubMed Central.

The ICMJE defines a clinical trial as any research project that prospectively assigns human subjects to intervention or comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Studies designed for other purposes, such as to study pharmacokinetics or major toxicity (e.g., Phase I trials), would be exempt from registering trials in a public registry such as ClinicalTrials.gov.

*Journal Citation:

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

Each publication, press release or other document that cites results from NIH grant-supported research must include an acknowledgment of NIH grant support and disclaimer such as “The project described was supported by Award Number U54DE019346 from the National Institute Of Dental & Craniofacial Research. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute Of Dental & Craniofacial Research or the National Institutes of Health.”
Below is additional wording for the acknowledgement of grant support:

For each publication that results from grant support provided by the NIDCR, grantees must include an acknowledgment of support and a disclaimer stating the following:

"This publication was made possible by Grant Number U54 DE 019346 from the NIDCR, a component of the National Institutes of Health (NIH)."

Award recipients are required to comply with the NIH Public Access Policy. This includes submission to PubMed Central (PMC), upon acceptance for publication, an electronic version of a final peer-reviewed manuscript resulting from research supported in whole or in part, with direct costs from National Institutes of Health. The author’s final peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. For additional information, please visit http://publicaccess.nih.gov/.
17 LITERATURE REFERENCES


SUPPLEMENTS/APPENDICES
## APPENDIX A: SCHEDULE OF EVENTS

### Follow-Up Schedule – Prenatal Period

<table>
<thead>
<tr>
<th>Procedures</th>
<th>Screening (Day -14 to 0)</th>
<th>Baseline (Day 0)</th>
<th>Study Visit 1 (4 weeks after baseline)</th>
<th>Study Visit 2 (6 weeks after baseline)</th>
<th>Study Visit 3 (1 month prior to due date)</th>
<th>Study Visit 4 (1 week after due date)</th>
<th>Premature Discontinuation</th>
<th>Study Visit 5 (3 months postpartum)</th>
<th>Study Visit 6 (6 months postpartum)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signed Consent Form</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<td>Assessment of Eligibility Criteria</td>
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<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study Intervention – Prenatal Period</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Questionnaires, demographic info</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Personal Contact</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
### Community-Based Intergenerational Oral Health Study

#### Follow-Up Schedule – Prenatal Period

<table>
<thead>
<tr>
<th>Procedures</th>
<th>Screening (Day –14 to 0)</th>
<th>Baseline (Day 0)</th>
<th>Study Visit 1 (4 weeks after baseline)</th>
<th>Study Visit 2 (6 weeks after baseline)</th>
<th>Study Visit 3 (1 month prior to due date)</th>
<th>Study Visit 4 (1 week after due date)</th>
<th>Premature Discontinuation</th>
<th>Study Visit 5 (3 months postpartum)</th>
<th>Study Visit 6 (6 months postpartum)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telephone Contact</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Postcard check-in</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assessment of Adverse Events</td>
<td>(X)</td>
<td>(X)</td>
<td>(X)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

### Follow-Up Schedule – Postpartum Period

<table>
<thead>
<tr>
<th>Procedures</th>
<th>Baseline – Visit 1 (9 months postpartum)</th>
<th>Study Visit 1 (Baseline + 6 weeks)</th>
<th>Study Completion (18 months postpartum)</th>
<th>Premature Discontinuation</th>
</tr>
</thead>
</table>

92
<table>
<thead>
<tr>
<th>Study Intervention – Postpartum Period</th>
<th>X</th>
<th>(X)</th>
<th></th>
<th>(X)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Questionnaires, demographic info for mother and child</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Personal Contact</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Telephone Contact</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Assessment of Adverse Events</td>
<td>(X)</td>
<td>(X)</td>
<td></td>
<td>(X)</td>
</tr>
<tr>
<td>Debrief</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

(X) – As indicated/appropriate.
APPENDIX B: PRENATAL MI INTERVENTION APPENDICES

Appendix A – Is Your Child At-Risk for Cavities Test
Appendix B – Segment 1 Video; Segment 2 Video
Appendix C – Benefits of Going to the Dentist; Segment 3 Video
Appendix D – Dental safety; Segment 4 Video
Appendix E – Dental fear; Segment 5 Video; Strategies Handout
Appendix F – Obstacles
Appendix G – Postcard for Follow-up Appointments
Appendix H – Postcard Reminder for 1 Month Prior to Birth
Appendix A – Is Your Child At-Risk for Cavities Test (Adapted from CAMBRA)

<table>
<thead>
<tr>
<th>Cavity Risk Indicators:</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have had dental decay and/or dental pain in past 12 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>My older children have had dental decay</td>
<td></td>
<td></td>
</tr>
<tr>
<td>My older children has special health care needs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I don’t have a dental office or clinic to go to regularly/ I don’t get regular dental care every 6 months</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Number of YES boxes checked: 

<table>
<thead>
<tr>
<th>Cavity Protective Factors:</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have not had a cavity or dental problems (pain) in the last three years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>My older children have a dental clinic they go to regularly/ They get regular dental care every 6 months</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Number of YES boxes checked: 

Score: 
1. Count the number of checked YES boxes in the Cavity Risk section and write number in the box, “Number of YES boxes checked”.

2. Count the number of checked YES boxes in the Cavity Protective section and write number in the box, “Number of YES boxes checked”.

3. Subtract the Cavity Protective number from the Cavity Risk number. Write number in this box. 

RISK SCORE

Stop- Go to Discussion Guide Protocol
Appendix B – Text for Video Segments 1 and 2

Segment 1:
One camera: Show mother holding jaw, looking pained (put cotton roll in vestibule of mouth to simulate swelling).

Voiceover: Cavities and broken teeth, we have learned, are the result of infections. A toothache is an advanced dental infection. (~ 10 seconds)

One camera: Show mother in kitchen preparing baby food. Mother hears baby crying. She picks up food and spoon, but drops spoon on floor. Mother picks up spoon, blows the fur off, puts it in her mouth and takes it to her baby (off camera).

Voiceover: Recently our research has shown that mothers with dental infections transmit these infections to their babies. There is no practical way to stop this transmission, as the bacteria are in saliva. (~ 15 seconds)

One camera: Show mother holding jaw, looking pained (put cotton roll in vestibule of mouth to simulate swelling) on the phone with a calendar open in front of her.

Voiceover: It is possible to reduce or eliminate risk make an appointment for a dental visit ... and keep it. Simple treatment eliminating mother’s dental infections will protect both the mother and the child. (~10 seconds)

Stop- Go to Discussion Guide Protocol

Segment 2:
Show video clip of infant with teeth smiling. [STOCK FOOTAGE AVAILABLE]

Voiceover: Not very long ago even dentists did not think baby teeth were important. Everyone knows you get two sets of teeth. But recent research has showed that if there are infections in the baby teeth, the permanent teeth become infected, often for a lifetime. (~23 seconds)

Stop- Go to Discussion Guide Protocol
Appendix C - Benefits of going to the dentist

Each rung on this ladder represents where various pregnant women are in perceiving the BENEFITS OF GOING TO THE DENTIST. Circle the number that indicates where you are now.

10: Going to the dentist would be a complete benefit to me.

9: There might be some problems in going to the dentist, but mostly there would be benefits.

8: The benefits of going to the dentist, and the possible problems of going, are equal.

7: There might be some benefits in going to the dentist, but mostly there would be problems.

6: There would be no benefits in going to the dentist. In fact, there would be serious problems if I went.
Does going to the dentist stop my dental problems?
--- No, going to the dentist did not stop my dental problem.
--- Yes, going to the dentist stopped my dental problems.

Do soft teeth seem to run in your family?
--- Yes
--- No

Dentists generally want to do work on teeth when there are no real problems.
--- Yes
--- No

The only dental problem worth working on is a tooth that is busted or in pain.
--- Yes
--- No

*Stop: Go to Discussion Guide Protocol*
Appendix C – Text for Video Segment 3:

(BATHROOM SETTING)
One camera: Show pregnant women looking into mirror at her teeth. Pregnant women still looking at teeth in mirror; she put in toothbrush and winces in pain.

Voice over: You may feel that your teeth are vulnerable, perhaps genetically, to dental disease and that dental treatment does not work for you. It is reasonable for people that feel this way stay away from dental treatment unless they really need it! Some people are more vulnerable to dental disease and it is true that the kind of dental treatment you’ve probably experienced ---drilling and filling and extractions may be needed but don’t work very well in stopping the disease. (~20 seconds)

(DENTAL CLINIC SETTING)
One camera: Pregnant women swishing rinse.
One camera: Pregnant women getting fluoride varnish painted on teeth by dental personnel.

Voice over: Now we know dental disease is caused by infections and (Fade in and out video of women swishing rinse) we have new approaches that work. For example, we have strong rinses that kill the bacteria that cause the infections and (Fade in/out video of dental person painting on fluoride varnish on pregnant woman) agents that we paint on the teeth to stop the disease and to protect them. All this is fairly new stuff. If you have “soft teeth” this new approach is worth looking into--- AND it is easy to swish and have stuff painted on your teeth. [~20 seconds]

Stop- Go to Discussion Guide Protocol
Appendix D – Dental Safety Questionnaire

Do you believe it is safe for your baby if you go to the dentist while you are pregnant?

- Yes, it is safe
- I am not sure it is safe
- No, I do not think it is safe

Do you believe it is safe for your baby if you go to the dentist while breastfeeding your baby?

- Yes, it is safe
- I am not sure it is safe
- No, I do not think it is safe

Stop- Go to Discussion Guide Protocol
Appendix D – Text for Video Segment 4

(MEDICAL CLINIC SETTING)
MD: “Hi Deanna. I hear you are thinking about going to the dentist. That's a great idea. Keeping your gums and teeth healthy during pregnancy is good for you and for your baby.” [~7 seconds]

Patient: “Some people say I should wait until after the baby is born. Is getting dental work done while I am pregnant safe for the baby?” [~5 seconds]

MD: “Yes. Getting your teeth cleaned and any needed dental work done is safe. It's a good idea to tell your dentist you are pregnant, but there isn't much difference in what the dentist needs to do to provide dental care to you if you are pregnant or not. You can have x-rays taken if needed to help the dentist know what treatment is needed. I am going to give/send you a letter to take to your dentist that specifies what he/she should do.” [~14 seconds]

(DENTAL CLINIC SETTING)
One camera: Show pregnant woman in dental chair being covered with lead apron (with thyroid collar). Show pregnant woman in dental chair being treated by dental personnel.

“During the x-ray, they will cover you with an apron-like shield and collar to protect you and your baby. Dental work including fillings, having teeth taken out, even a root canal can be done safely during pregnancy. During pregnancy, you might notice your gums are swollen or bleed more easily. A routine dental cleaning can really help keep your gums clean and keep them from getting infected. So, there are lots of good reasons to go!” [~15 seconds]

“One other thing, if you have dental or other pain while you are pregnant use only Tylenol. Do NOT take aspirin as it can lead to bleeding. It's best to avoid other pain relievers too, like ibuprofen.” [~10 seconds]

Stop- Go to Discussion Guide Protocol
Appendix E – Dental Fear questions:

1. Has fear of dental work ever caused you to put off making an appointment?
   1. Never
   2. Once or twice
   3. A few times
   4. Often
   5. Nearly always

2. Has fear of dental work ever caused you to cancel or not appear for an appointment?
   1. Never
   2. Once or twice
   3. A few times
   4. Often
   5. Nearly always

Stop- Go to Discussion Guide Protocol
Appendix E – Text for Video Segment 5:

*Show SLIDES of dental fear cartoons*

Voice over: Dental fear is common and keeps people from getting their needs met. So common there are cartoons about this in the funny pages. About 30 percent of people avoid dental care because of fear. What can you do about this fear? [~15 seconds]

*One camera: Show pregnant woman thinking and then writing a list*

Voice over: Think about what you need to be successful at the dentist.

*Show SLIDES of items written on the list below; in parentheses are Voiceovers*

1. No surprises? (I need to know what will happen)
2. Be sure I am good and numb. (I hate pain)
3. Short rest breaks (Can really help)
4. Something to ease my anxiety? (It works for some people)
5. Someone to hold my hand? (I know who to ask)
6. A pre-arranged signal for pain? (Yes!)

*One camera: Pregnant woman in the dental chair talking to dental personnel*

Pregnant Woman: “The last visit I had I was not numb when the dentist drilled. Could the dentist give me extra numbing medicine?”

Voice over: Talk to the dentist or hygienist! Most dentists and hygienists would find this a reasonable request. [~8 seconds]

*One camera: Scenario of dental personnel giving patient mirror and talking and pointing as working.*

Voice over: If you are the kind of person that likes to know what is going on, ask for a mirror or even technical information. [~8 seconds]

*One camera: Video of pregnant woman with ipod, doing deep breathing.*

*One camera: Video of pregnant woman walking outside OR sitting on bench looking calm and serene.*

Voice over: If you do not like to pay attention, bring something to pay attention to, do breathing exercises, and imagine you are at a place that is warm, safe and comfortable — using one sense at a time. For example, imagine what it smells like on your favorite walk; what are the sounds; what does it feel like to take a step on the trail? (14 seconds)

**Stop- Go to Discussion Guide Protocol**
Appendix E – Handout of Strategies:

1. No surprises. If you are the kind of person that likes to know what is going on, ask for a mirror or even technical information.

2. Be sure I am good and numb.

3. Short rest breaks

4. Can I have something to help make me less anxious? If you do not like to pay attention, bring something to pay attention to, do breathing exercises, and imagine you are at a place that is warm, safe and comfortable — using one sense at a time. For example, imagine what it smells like on your favorite walk through the woods; what are the sounds; what does it feel like to take a step on the trail?

5. Can a friend or loved one holding my hand help?

6. Would a pre-arranged signal that I am in pain or very upset help?
Appendix F - Obstacles—getting to the dentist

Which of the following could get in the way of you going to the dentist?

----Transportation?

--- Baby sitting?

--- Getting time off from work or other responsibilities?

--- Finding someone to go with me?

--- Communicating/interacting with front office staff and dentist (in person and on the phone)?

--- Anything else?

Stop- Go to Discussion Guide Protocol
Appendix G – Postcard for Follow-up Appointments
(1 month; 6 weeks after MI Counseling)

Text of postcard:

Date
Dear ______________

(Space for personal comments, e.g., I enjoyed meeting you, etc.).

This postcard is sent to remind you that I will call you on a _______ (day of week) _________
(day and month) at _________ (time). We will talk about how well your plan is working and will,
if needed, try to make adjustments. (In pen, I am eager to speak to you again).

Regards,___________________  .

Telephone (provide telephone number) ____________ to change your telephone appointment.
Appendix H – Postcard Reminder for 1 Month Prior to Birth

Text of postcard:

Dear _____________

Space for personal comments, e.g., *I have been thinking about you.*

We at Baby Smiles want to keep in touch with your family. How well is the plan working? 

(In pen) *Is everything okay? Please call me if you have a problem.*

Regards, Name of county counselor.

Telephone ____ _____ _____

*Baby Smiles* 

Protecting Your Child's Teeth Begins In Pregnancy
APPENDIX C: POSTPARTUM MI INTERVENTION APPENDICES

Appendix A – Postcard for Follow-up Appointments (1 month; 6 weeks)
Appendix B – Postcard Reminder for 6 Month Appointment
Appendix A – Postcard for Follow-up Appointments

(1 month; 6 weeks after MI Counseling)

Text of postcard:

Date
Dear ____________

(Space for personal comments, e.g., I enjoyed meeting you, etc.).

This postcard is sent to remind you that I will call you on a _______ (day of week) _________ (day and month) at _________ (time). We will talk about how well your plan is working and will, if needed, try to make adjustments. (In pen, I am eager to speak to you again).

Regards,__________________.

Telephone (provide telephone number) ____________ to change your telephone appointment.

Baby Smiles
Protecting Your Child’s Teeth Begins in Pregnancy
Appendix B – Postcard Reminder for 6 Month Appointment

Text of postcard:

Dear ________________

Space for personal comments, e.g., I have been thinking about you and _____(name of child).

This postcard is sent to remind you of your appointment on a _______ (day of week) _______ (day and month) at _________ (time). We will talk about how well your plan is working and will, if needed, try to make adjustments. (In pen, I am eager to speak to you again).

Regards,___________________ .

Telephone (provide telephone number) ___________ to change your appointment.
APPENDIX D: STUDY QUESTIONNAIRES

Questionnaire Packet

Baby Smiles Study Baseline Questionnaire

1. Background Information

   a. What is your due date?
      ____ ____ / ____ ____ / ____ ____

   b. What is your birth date?
      ____ ____ / ____ ____ / ____ ____

   c. What is your race/ethnicity?
      Please check all that apply.
      1 American Indian or Alaskan Native
      2 Asian or Pacific Islander
      3 Black, not of Hispanic origin
      4 Hispanic
      5 White, not of Hispanic origin
      6 Other (please specify)
         ______________________

   d. What is your marital status?
      Please check one box below.
      1 Married
      2 Single / never married
      3 Separated
      4 Divorced
5. Living with partner
6. Widowed
7. Other (please specify)

---

e. Do you have children?

```
1. Yes
2. No
```

Please tell us how many children you have in each of the following age groups:

<table>
<thead>
<tr>
<th># of children</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>i</td>
<td>Less than 1 year old</td>
</tr>
<tr>
<td>ii</td>
<td>1 - 2 years old</td>
</tr>
<tr>
<td>iii</td>
<td>3 - 5 years old</td>
</tr>
<tr>
<td>iv</td>
<td>6 - 12 years old</td>
</tr>
<tr>
<td>v</td>
<td>13 - 18 years old</td>
</tr>
<tr>
<td>vi</td>
<td>More than 18 years old</td>
</tr>
</tbody>
</table>

f. What is the highest level of education you have completed?

Please check one box below.

```
1. Less than high school diploma
2. High school diploma / GED
3. Trade/vocational training
4. Some college
5. 2 year college degree
6. 4 year college degree
7. Master’s degree
8. Doctoral degree
```

2. Your experience with the dentist

a. When was the last time you went to the dentist? Please check one box below.
1. Less than 6 months ago
2. Between 6 and 12 months ago
3. Between one and two years ago
4. More than two years ago

b. What was the primary reason for your last dental visit? Please check one box below.
   1. Emergency (tooth ache, broken tooth, pain)
   2. Check-up and cleaning
   3. Scheduled treatment (fillings, crowns, bridges, etc.)
Oral Health Impact Profile – short form (OHIP-14) (from de Oliveira, Nadanovsky, 2006; original by Slade, 1997)

<table>
<thead>
<tr>
<th>Question</th>
<th>Never</th>
<th>Hardly Ever</th>
<th>Occasionally</th>
<th>Fairly Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you had trouble <em>pronouncing any words</em> because of problems with your teeth, mouth, or dentures?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Have you felt that your <em>sense of taste</em> has worsened because of problems with your teeth, mouth, or dentures?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Have you had <em>painful aching</em> in your mouth?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Have you found it <em>uncomfortable to eat any foods</em> because of problems with your teeth, mouth, or dentures?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Have you been <em>self-conscious</em> because of your teeth, mouth, or dentures?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Have you felt tense because of your problems with teeth, mouth, or dentures?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Has your <em>diet been unsatisfactory</em> because of problems with your teeth, mouth, or dentures?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Have you had to <em>interrupt meals</em> because of problems with your teeth, mouth, or dentures?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Have you found it <em>difficult to relax</em> because of problems with your teeth, mouth, or dentures?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Have you been a bit <em>embarrassed</em> because of problems with your teeth, mouth, or dentures?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Question</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Have you been a bit <em>irritable with other people</em> because of problems with your teeth, mouth, or dentures?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you had <em>difficulty doing your usual jobs</em> because of problems with your teeth, mouth, or dentures?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you felt that life in general was <em>less satisfying</em> because of problems with your teeth, mouth, or dentures?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you been <em>totally unable to function</em> because of problems with your teeth, mouth, or dentures?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Early Child Oral Health Impact Scale – (from Pahel, Rozier, Slade, 2007) – Modified for 9 & 18 month visit

<table>
<thead>
<tr>
<th>Questions</th>
<th>Never</th>
<th>Hardly ever</th>
<th>Occasionally</th>
<th>Often</th>
<th>Very often</th>
<th>Don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>How often do you think your child will have pain in the teeth, mouth or jaws?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How often do you think your child (See a-h) ... because of dental problems or dental treatments?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. will have difficulty drinking hot or cold beverages</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. will have difficulty eating some foods</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. will have difficulty pronouncing any words</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. will miss preschool, daycare, or school</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e. will have trouble sleeping</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>f. will be irritable or frustrated</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>g. will avoid smiling or laughing when around other children</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>h. will avoid talking with other children</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How often will you or another family member (See a-c) ... because of your child’s dental problems or dental treatments?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. will be upset</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. feel guilty</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. will need to take time off from work</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How often will your child have dental problems or dental treatments that have a financial impact on your family?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Modified Dental Anxiety Scale** (Humphris GM et al., 1995; from Leena Bitar’s thesis)

“I’m going to ask you some questions about how you would feel at the dentist. Please tell me how anxious you get, if at all, at the dentist.”

<table>
<thead>
<tr>
<th></th>
<th>Not Anxious</th>
<th>Slightly Anxious</th>
<th>Fairly Anxious</th>
<th>Very Anxious</th>
<th>Extremely Anxious</th>
</tr>
</thead>
<tbody>
<tr>
<td>If you went to the dentist for TREATMENT TOMORROW, how would you feel?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>If you were sitting in the WAITING ROOM (waiting for treatment), how would you feel?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>If you were about to have a TOOTH DRILLED, how would you feel?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>If you were about to have your TEETH SCALED AND POLISHED, how would you feel?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>If you were about to have a LOCAL ANESTHETIC INJECTION in your gum, above an upper back tooth, how would you feel?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

Many people dislike going to the dentist. Do you think your feelings will get in the way of taking your child to the dentist?

YES  NO
THINKING ABOUT GOING TO THE DENTIST

Each rung on this ladder represents where various pregnant women are in their THINKING ABOUT GOING TO THE DENTIST. Circle the number that indicates where you are now.

10: I am taking action to go to the dentist.
9: I am starting to think about how to go to the dentist.
8: I think I should go to the dentist, but I am not quite ready.
7: I think I need to consider going to the dentist someday.
6: No thoughts about going to the dentist.
5: I am starting to think about how to go to the dentist.
4: I am taking action to go to the dentist.
3: I think I should go to the dentist, but I am not quite ready.
2: I think I need to consider going to the dentist someday.
1: No thoughts about going to the dentist.
0: No thoughts about going to the dentist.
THINKING ABOUT TAKING CHILD TO THE DENTIST

Each rung on this ladder represents where various parents are in their THINKING ABOUT TAKING THEIR CHILD TO THE DENTIST. Circle the number that indicates where you are now.

- **10**: I am taking action to take my child to the dentist.
- **9**: I am starting to think about how to take my child to the dentist.
- **8**: I think I should take my child to the dentist, but I am not quite ready.
- **7**: I think I need to consider taking my child to the dentist someday.
- **6**: No thoughts about taking my child to the dentist.
Perceived Stress Scale – *(from Cohen et al., 1983; Cohen & Williamson, 1988)*

<table>
<thead>
<tr>
<th>Question</th>
<th>Never</th>
<th>Almost Never</th>
<th>Sometimes</th>
<th>Fairly Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>In the last month, how often have you been upset because of something that happened unexpectedly?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>In the last month, how often have you felt that you were unable to control the important things in your life?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>In the last month, how often have you felt nervous and “stressed”?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>In the last month, how often have you felt confident about your ability to handle your personal problems?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>In the last month, how often have you felt that things were going your way?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>In the last month, how often have you found that you could not cope with all the things that you had to do?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>In the last month, how often have you been able to control irritations in your life?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>In the last month, how often have you felt that you were on top of things?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>In the last month, how often have you been angered because of things that were outside of your control?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
### Center for Epidemiologic Studies Depression Scale (CES-D)

The 20 items below refer to how you have felt and behaved during the last week. Check the box that shows how you felt during the last week.

<table>
<thead>
<tr>
<th>Question</th>
<th>Rarely or none of the time (&lt;1 day)</th>
<th>Some or a little of the time (1-2 days)</th>
<th>Occasionally or a moderate amount of the time (3-4 days)</th>
<th>Most or all of the time (5-7 days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I was bothered by things that don’t usually bother me.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I did not feel like eating; my appetite was poor.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I felt that I could not shake off the blues even with the help of my family or friends.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I felt that I was just as good as other people.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I had trouble keeping my mind on what I was doing.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I felt depressed.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I felt everything I did was an effort.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I felt hopeful about the future.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I thought my life had been a failure.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I felt fearful.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>My sleep was restless.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I was happy.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I talked less than usual.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I felt lonely.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>People were unfriendly.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I enjoyed life.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I had crying spells.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I felt sad.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I felt that people disliked me.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I could not get &quot;going&quot;.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Oral Health Self-Efficacy (OHSE) – (Adair et al, 2004)

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>I don’t know how to brush my child’s teeth properly</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>We cannot make our child brush his/her teeth twice daily</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>If our child does not want to brush his/her teeth every day we don’t feel we should make him/her</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>It would not make any difference to our child getting tooth decay, if we helped him/her brush every day</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>As a family, we intend brushing our child’s teeth for him/her</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>We intend brushing our child’s teeth for him/her twice a day</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>It would be too stressful to say no to my child when they want sweets</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>In our family it would be unfair not to give sweets to our child every day</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>In our family we feel it would be difficult for us to stop our child from having sugary foods and drinks between meals</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>We can prevent tooth decay in our child by reducing sugary foods and drinks between meals</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>As a family, we intend controlling how often our child has sugary foods or drinks between meals</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

### Oral Health Fatalism (OHF) - (Adair et al, 2004)

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>No matter what we do, our child is likely to get tooth decay</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>It is just bad luck if our child gets tooth decay</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>If our child gets tooth decay, it is by chance</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
### Knowledge of Bottle Use (KBU) (items from Finlayson et al, 2005 and Adair, 2004 articles) –

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Putting a baby to bed with a bottle helps the child to be better fed.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Putting a baby to bed with a bottle helps the child sleep better.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Putting a baby to bed with a bottle helps the child to gain weight and grow.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>There is nothing wrong with putting a baby to bed with a bottle.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
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</tbody>
</table>

### Knowledge of Children’s Oral Hygiene (KCOH)

<table>
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<tr>
<th>Statement</th>
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<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cavities in baby teeth don’t matter since they fall out anyway.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Keeping baby teeth clean is not very important; after all, they fall out.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>There is not much I can do to stop my child from developing dental cavities.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Children don’t need to brush every day until they get their permanent teeth.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Children don’t really need their own toothbrush until all their teeth come in.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>If we use fluoridated toothpaste for our child, it will prevent tooth decay</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
EVEN'S SNACKING QUESTIONNAIRE
Child Feeding Information

14. Has the child ever been breast fed? (check one)
   _____ yes
   If yes, at what age was the breast feeding stopped? ____________
   (put 0 if still breast feeding)
   How many times a day does the child usually breast feed? __________
   Was the child breast fed before going to sleep? (circle one) yes no
   _____ no
   _____ don't know

15. Is the child using a bottle now? (check one)
   _____ yes
   If yes, how old was the child when bottle feeding started? __________
   How many times a day does the child usually bottle feed? __________ (Go to ?18)
   _____ no, never used bottle (Go to ?20)
   _____ no, used bottle in the past
   If no, how old was the child when the bottle feeding started? __________
   How old was the child when bottle feeding stopped? ________________ (Go to ?18)
   _____ don't know (Go to ?18)

16. Do you now give the child a bottle as he/she goes to sleep? (check one)
   _____ yes
   If yes, how many times a day? ____________
   What is the bottle usually filled with? ______________________________
   _____ no
   _____ don't know

17. Did you in the past give the child a bottle as he/she went to sleep? (check one)
   _____ yes
   If yes, how many times a day? ____________
   What was the bottle usually filled with? ______________________________
   _____ no
   _____ don't know

18. Do you and your child share the same utensils (spoons, forks) during feeding time?
   _____ yes
   _____ no

19. Do you chew the child's food before giving it to the child?
   _____ yes
   _____ no

Dental History
20. How old was the child when his/her teeth first appeared? ____________

21. Have you ever tried to clean your child's teeth?
   _____ yes
   If yes, what did you use?
   _____ toothbrush
   _____ cloth
   _____ other (please specify) ____________________
   _____ no

22. Does the child have his/her own toothbrush? (check one)
   _____ yes
   If yes, since what age? ______________
   _____ no

23. Is toothpaste used for child’s toothcleaning? (check one)
   _____ yes
   If yes, what brand? ______________________________
   Since what age? ______________
   _____ no

24. How often are the child’s teeth usually cleaned or brushed? (check one)
   _____ don’t clean or brush teeth
   _____ less than once a week
   _____ once or twice a week
   _____ about every other day
   _____ almost every day
   _____ once a day
   _____ twice a day
   _____ more than twice a day
   _____ don’t know

25. When are the child’s teeth usually cleaned or brushed? (check all that apply)
   _____ don’t clean or brush teeth
   _____ morning
   _____ afternoon
   _____ evening/before bed

26. Who usually cleans the child’s teeth?
   _____no one
   _____ the child
   _____ mother
   _____ other

27. Has the child ever seen a dentist before? (check one)
_____ yes
If yes, why? ________________________________

What was the child's age when he/she first went to the dentist? ___________

How many times has the child gone to the dentist? _______________________

_____ no

28. Has the child's primary caregiver had toothaches, cavities, or bleeding gums in the past six months?

_____ yes

_____ no

Residence History

29. Since the birth has the child lived anywhere else?

_____ no

_____ yes, list which city or county and time at each location:
____________________________________________________________________
____________________________________________________________________

Medical History

30. Please list a current contact or family member who DOES NOT LIVE AT YOUR ADDRESS.
____________________________________________________________________
____________________________________________________________________

31. What is the overall health of the child? (check one)

_____ excellent

_____ very good

_____ good

_____ fair

_____ poor

_____ don’t know

32. Has the child ever had any major illnesses?

_____ yes
If yes, which ones? ______________________________________________________

_____ no

33. Has the child ever taken antibiotics?

_____ yes
If yes, why? __________________________________________________________
For how long? ___________________________

_____ no
34. Does the child routinely take vitamins?
   _____ yes
   If yes, which brand? ____________________________________________
   _____ no

35. Does the child routinely take fluoride tablets?
   _____ yes
   _____ no

36. Does the child routinely take fluoride drops?
   _____ yes
   _____ no

37. On a scale of 1 - 5 with 1 being easy and 5 being difficult how would you rate the child's temperament? (circle a number)
   1(easy)  2  3  4  5(difficult)

Dietary Questionnaire

38. Does the child eat any solid foods?
   _____ yes
   _____ no

39. Does the child drink anything besides milk?
   _____ yes
   If yes, name the drinks _______________________________________
   _____ no

40. Does the child usually: (circle one)
   eat or drink breakfast?    yes / no
   eat or drink a morning snack?   yes / no
   eat or drink lunch?    yes / no
   eat or drink an afternoon snack?   yes / no
   eat or drink dinner?    yes / no
   eat or drink a snack right before bedtime?    yes / no

41. How many meals does the child usually have each day? ________________

42. How many snacks (foods & drinks) does the child usually have each day? ________________

43. What are the most common foods that the child eats as snacks?
   ____________________________________________________________
   ____________________________________________________________

44. What are the most common drinks the child has as snacks?
   ____________________________________________________________
45. Do you use sweet snacks to get the child to behave?  
   _____ yes  
   _____ no

46. Do you use sweet snacks as a reward for the child?  
   _____ yes  
   _____ no

47. How often did the child snack on the following foods last month?

<table>
<thead>
<tr>
<th>Snack Food</th>
<th>never</th>
<th>rarely</th>
<th>1/week</th>
<th>2-3/week</th>
<th>1/day</th>
<th>2-3/day</th>
<th>4+/day</th>
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</table>
Tooth brushing frequency (1-week):
What was the total number of times the child’s mouth/teeth was cleaned/brushed in last week?
Who did the cleaning/brushing?