

# **Stakeholder Engagement and Multi-Risk Assessment in Dental Care Settings**

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## LIST OF ABBREVIATIONS

AE	Adverse Event/Adverse Experience
CC	Coordinating Center
CDT	Current Dental Terminology
CFIR	Consolidated Framework for Implementation Research
CFR	Code of Federal Regulations
CPCQ	Change Process Capability Questionnaire
DHHS	Department of Health and Human Services
EBP	Evidence-Based Practice
FFR	Federal Financial Report
GPI	Grant Principal Investigator
HIT	Health Information Technology
IRB	Institutional Review Board
MOP	Manual of Procedures
MRA	Multi-Risk Assessment
N	Number (typically refers to participants)
NADP	National Association of Dental Plans
NND	National Network Director
NIDCR	National Institute of Dental and Craniofacial Research, NIH, DHHS
NIH	National Institutes of Health
OHRP	Office for Human Research Protections
PBRN	Practice-Based Research Network
PCP	Primary Care Provider
QA	Quality Assurance
QC	Quality Control
RC	Regional Coordinator
SA	South Atlantic
SAE	Serious Adverse Event/Serious Adverse Experience
SMS	Survey Management System
SPI	Study Principal Investigator
UAB	University of Alabama
UP	Unanticipated Problems

UF	University of Florida
UF – SRC	University of Florida Survey Research Center
US	United States

## **STATEMENT OF COMPLIANCE**

The study will be conducted in accordance with the Code of Federal Regulations (CFR) on the Protection of Human Subjects (45 CFR Part 46), and the National Institute of Dental and Craniofacial Research (NIDCR) Clinical Terms of Award. All personnel involved in the conduct of this study have completed human subjects protection training.

## **SIGNATURE PAGE**

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this study 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 United States (US) federal regulations and guidelines.

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Regional Directors:

Signed: \_\_\_\_\_ Date: \_\_\_\_\_

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Title: Regional Director, South Atlantic Region



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## SIGNATURE PAGE- NETWORK STAFF

*A copy of this page is to be signed by all Steering Committee members, Regional Coordinators, and other National Dental Practice-Based Research Network (PBRN) staff members responsible for conducting any portion of the study (if not already designated to sign the protocol above). The signature page should be printed, signed, then scanned into a PDF document and submitted to the Coordinating Center ([NDPBRN-helpdesk@westat.com](mailto:NDPBRN-helpdesk@westat.com)) for storage on the Internal Website.*

The signature below constitutes:

- 1) acknowledgement of having read this protocol version (as indicated in the upper right corner of this page) and the attachments, and
- 2) an assurance that this individual will conduct all of his or her assigned study tasks 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 guidelines.
- 3) an assurance that this individual will read and follow all study plans applicable to his/her role on the study (e.g. Regional Coordinators will read and follow the Manual of Procedures (MOP), Practice Training Manual, Clinical Monitoring Plan, and other applicable plans developed in the future).

Signed: \_\_\_\_\_ Date: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

## PROTOCOL SUMMARY

**Title:** Stakeholder Engagement and Multi-Risk Assessment in Dental Care Settings

**Précis:** The dentist's office may be an important setting for conducting multi-risk assessments (MRAs) for oral and physical health risks to increase opportunities for early assessment of and intervention for risk behaviors. This study will characterize dental practitioners' (dentists and hygienists), dental payers', and patients' attitudes about: (a) conducting/participating in MRAs during dental visits; and (b) providing/receiving follow-up counseling about and referrals for identified risks. An analysis also will be conducted of the dentists' and dental hygienists' scope of practice documents to determine if there are any regulatory barriers for conducting MRAs, risk behavior counseling, and referrals.

**Objectives:** The primary objective of this study is to describe dentist and hygienist attitudes and willingness towards conducting multi-risk assessments (MRAs) in dental offices, providing counseling, and making referrals for health risk behaviors and medical conditions identified through screening.

The secondary objectives of this study are to: describe organizational and external factors that may influence dentist and hygienist attitudes and willingness towards conducting MRAs, providing counseling, and making referrals in dental practices; describe dental patients' attitudes toward completing MRAs in dental practices and discussion of their health risk behaviors with dentists and/or hygienists; and examine dental payer recommendations about the feasibility of conducting MRAs in dental practices.

**Outcomes:** For the primary objective, dental practitioner questionnaires will be used to assess the following primary outcome measures: (1) dentists' and hygienists' current MRA practice patterns including the number and type of health risks screened for during a dental visit; (2) practitioner perceived self-efficacy in conducting MRAs; (3) belief in effectiveness of MRAs; and (4) practitioner recommendations for conducting MRAs in their practices and providing counseling and making referrals based on those assessments. All data will be self-reported by consenting, participating dental practitioners and will focus on screening for the following risk behaviors and medical conditions: tobacco use; alcohol use; behaviors that may contribute to contracting HIV and other sexually transmitted infections; raising patient awareness about dental risks associated with the consumption of foods and beverages with high sugar content; risk factors for diabetes, hypertension, and heart disease, including weight, inactivity, family history of the disease (s), and the presence of diabetes, hypertension, and heart disease.

The following secondary outcomes will be assessed: 1) the relationships among dental practices' organizational factors (capacity for change and their resources to sustain change as measured by scores on the Change Process Capability Questionnaire (CPCQ) and the Adaptive Reserve Questionnaire), external factors (e.g., reimbursement) and practitioner willingness to conduct MRAs; 2) patients' attitudes towards completing MRAs in dental practices and discussion of their health risk behaviors with dental practitioners; 3) dental payer perspectives about the feasibility of conducting MRAs in dental practices.

**Population:**

Dental Practitioner Survey: All survey-eligible South Atlantic (SA) region practitioners (approximately 870 practitioners; 469 dentists and 401 hygienists) will be invited to participate in the survey. Based on previous National Dental PBRN surveys conducted in this network, we expect a dental practitioner participation rate of 60% using an online approach only. The goal is to achieve an 80% response rate. Therefore, the survey invitation will be sent via email and will include an option for the dental practitioner to request a paper version of the survey. Those dental practitioners requesting a paper version will be sent a survey packet. If there is less than a 40% response rate, paper surveys may be sent as part of follow-up. Dental Patient Surveys: Approximately 30 dental practitioners in the SA region will administer surveys to approximately 900 dental patients (approximately 30 patients per practitioner).

Dental Plan Dental Director: Approximately twenty dental directors will be approached and invited to participate in telephone in-depth interviews.

**Number of Sites:**

- 1: University of Florida
- 2: 30 SA Region Dental Practices

**Study Duration:**

12 months

**Practitioner  
Participant  
Participation  
Duration:**

1: Dental practitioner survey respondents will complete the one-time cross-sectional survey (up to 30 minutes).

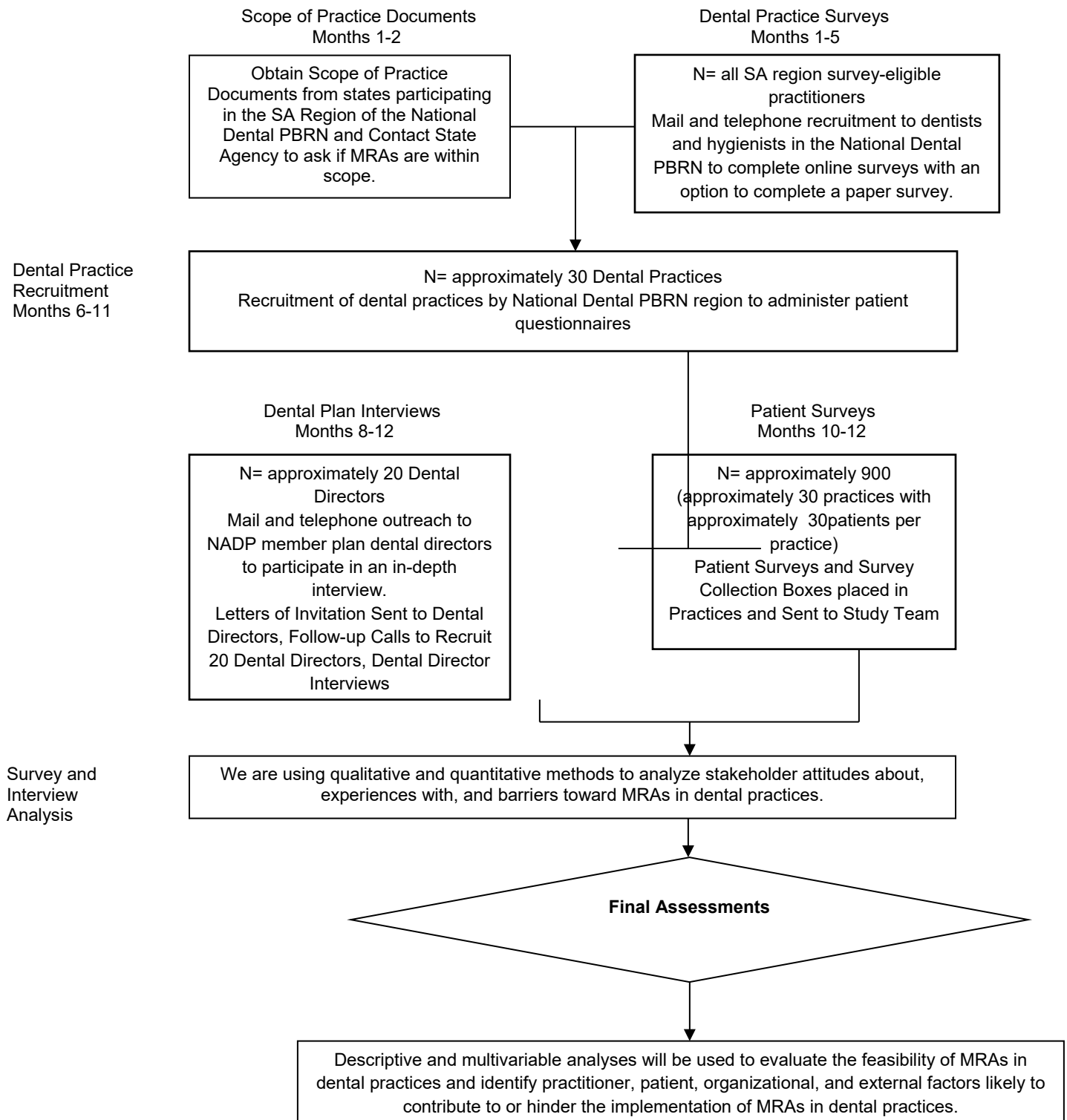
2: Approximately 30 practitioners will be recruited from among those completing the dental practitioner surveys and asked to recruit patients to complete a patient questionnaire. The 30 participating practitioners will recruit dental patients over approximately two months. Patients will be asked to complete a questionnaire prior to and after their routine dental check-up visits (up to 15 minutes total).

3: Dental Plan Dental Directors will participate in a one-time in-depth telephone interview (30 to 45 minutes).

**Estimated Time to  
Complete  
Enrollment:** 8 months

## Schematic of Study Design:

### PARTICIPANT RECRUITMENT AND SURVEY QUESTIONNAIRE ADMINISTRATION



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- Dr. Stephanie Staras (Study Co-Investigator)

## 2 INTRODUCTION: BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

### 2.1 Background Information

Oral health is inextricably linked to overall physical health and is significantly impacted by an individual's health behaviors. Tobacco use, risky drinking, and high consumption of sugar in food and drinks are common health risk behaviors in adolescents and adults. These behaviors tend to co-occur and significantly contribute to poor physical and oral health and high health care expenditures.<sup>1-3</sup> For example, unhealthy diet is a substantial contributor to the development of diabetes, which affects an estimated 25.6 million individuals who have the disease and another estimated 79 million with pre-diabetes.<sup>4</sup> Tobacco and alcohol use contribute to an increased risk for a range of physical and oral health problems including severe periodontitis,<sup>5</sup> hypertension, cancer, and others.<sup>6</sup> Engagement in unsafe sexual practices is another frequently occurring health risk behavior that contributes to significant morbidity, including contracting HIV.<sup>7</sup>

MRAs are a key component of **prospective health care**, which emphasizes prevention, screening, and *preemptive intervention* to reduce the morbidity and mortality associated with risk behaviors.<sup>8</sup> Conducting MRAs is the first step in identifying individual health risks to better inform overall diagnoses and treatment plans and to ensure that appropriate counseling and referrals are made. Health care provider counseling is effective in achieving behavioral change for risk behaviors such as smoking, alcohol misuse, and sexual risk taking.<sup>9</sup> *Despite the importance of MRAs and their benefit, numerous studies have documented low levels (3-25%) of health risk behavior assessment in primary-care settings; particularly among adolescents.*<sup>10,11</sup> Regardless, there is growing evidence that health risk screening for particular conditions (e.g., diabetes, tobacco use) in dentists' offices could increase opportunities to provide counseling and referrals for identified risks.<sup>12-14</sup> Lamster and Eaves suggest that "a broad number of primary health care activities may be conducted in the dental office, such as screening for hypertension, diabetes mellitus; and smoking prevention and cessation activities."<sup>15</sup> It is not known if offering MRAs would be acceptable to dentists, their patients and payers, and if so, whether MRAs would enhance dental patients' opportunities to receive needed counseling and referrals.

**Conceptual Framework:** The Consolidated Framework for Implementation Research (CFIR) guides this proposed study (Figure 1).<sup>16</sup> The CFIR emphasizes that organizational, stakeholder (practitioner, patient, and payer) and external factors influence the implementation of new interventions. This framework further emphasizes the importance of adapting interventions to meet local needs and practice workflow.

We selected the CFIR to guide this study because it (1) emphasizes stakeholder engagement to understand local priorities and practice workflow in order to determine if MRAs can be successfully implemented in a particular setting; and (2) focuses on understanding and working within the context of organizational, practitioner, patient, and external factors when implementing new interventions.<sup>16</sup>

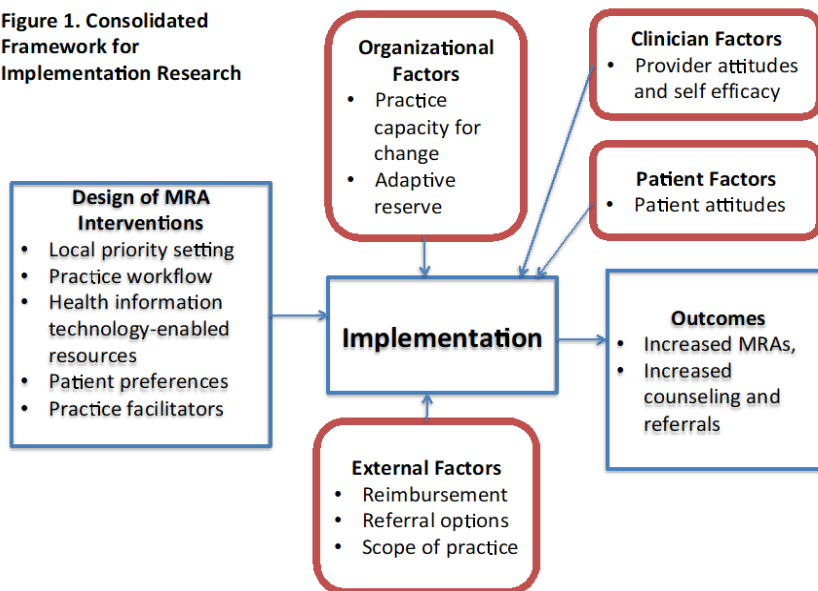
**In our proposed study, we are specifically focusing on four components of the CFIR (noted in red on Figure 1):**

- 1) **Dental organizational factors** including practice capacity to implement new interventions (change capacity),<sup>17</sup> and adaptive reserve, (ability to sustain change),<sup>18</sup>
- 2) **Dental practitioner (dentist and hygienist) factors** including current MRA



- practices, perceived self-efficacy in conducting MRAs, and beliefs about the effectiveness of (a) MRAs, (b) brief counseling, and (c) referrals to address identified risks; and
- 3) **Patient factors** including attitudes toward (a) answering questions about health risk behaviors during a dental visit; and (b) receiving education from a dentist and/or hygienist regarding identified health risks; and
  - 4) **External factors** including: payer attitudes about MRAs, reimbursement barriers for screening, counseling, and referrals, and state scope of practice regarding dentist and hygienist administration of MRAs, counseling and referrals.

Figure 1. Consolidated Framework for Implementation Research



## 2.2 Rationale

A previous National Dental Practice-Based Research Network study involving 498 patients showed that blood glucose testing was well received by patients and practitioners, supporting the feasibility of implementation of this test in community dental practices.<sup>12</sup> In addition, other studies have demonstrated the feasibility of conducting risk assessments and screening for particular conditions (e.g.,

hypertension, diabetes).<sup>13,19</sup> Further, some studies conducted in physician primary care practices have shown that even brief interventions can raise patients' awareness about the risks associated with tobacco use and may contribute to quitting.<sup>20,21</sup> However, none of the dental studies have focused on comprehensively assessing health risks. Nor have any studies demonstrated acceptance by dental practitioners for conducting MRAs. *More comprehensive assessments can be helpful for identifying health risks that may be co-occurring such as hypertension, diabetes, and tobacco and substance use.*<sup>22</sup> *Through conducting MRAs and other preventive care activities, dental practitioners (dentists and hygienists) may play an important role in increasing access to care and initiating counseling aimed at reducing health risks.*<sup>12-14,23</sup>

Dental practitioners have differing perspectives on the extent to which it is feasible for them to conduct MRAs in their practices. Concerns include: lack of time; financial constraints including cost of submitting claims, delays in payment, and reimbursement amounts; office layout, which may not provide sufficient privacy for discussion of MRA results; and barriers to making referrals for identified risks.<sup>24</sup>

The perspective of dental payers about conducting MRAs is also important. Dentists may be more equipped to conduct MRAs, provide counseling, and make referrals if they are reimbursed for this care. During a focus group with representatives from two major national dental plans, DentaQuest and Managed Care of North America (MCNA), Inc., participants noted that Current Dental Terminology Codes (CDT) such as S9445 (patient education) could be used to reimburse dentists. However, the participants also noted that financial incentives for MRAs would likely result in increased costs to dental plans, which affect their profitability. Some dental plan participants were supportive of MRAs in dental settings *only if* there was a linkage to medical primary care practices, so that referrals could be made from physicians to dentists and vice-versa for identified physical and oral health needs.<sup>25</sup> The payers were supportive of this linkage to reduce barriers to referrals and to increase the patient base for the dentists. The findings from this unpublished focus group are similar to those of other published studies that identified a lack of reimbursement as a barrier to implementing health risk assessment in dental practices.<sup>26–28</sup>

Finally, patients' perspectives regarding discussion of their health risk behavior with dental providers are important. Patients have varying attitudes toward sharing this information with physicians in primary care settings and little is known about their attitudes toward discussing their health risk behaviors with dental practitioners.<sup>2</sup>

In summary, numerous studies have documented the benefits associated with engaging stakeholders in determining the feasibility and design of interventions.<sup>29</sup> Currently, most health risk assessments in dental practices are limited to tobacco use and a self-report of chronic oral and physical health conditions. Some studies have documented the feasibility of providing hypertension, glucose, and HIV screening in dental settings. However, these studies have primarily occurred in limited practice settings (e.g., community centers) and typically focus on particular health risks or conditions, and to our knowledge, despite the positive findings, MRAs have not been widely adopted in dental settings.<sup>13</sup> *More information about dentist, dental hygienist, dental plan, and patient stakeholder attitudes toward MRAs in diverse dental practice settings is needed to determine if the conduct of MRAs is feasible and acceptable to stakeholders.*<sup>13</sup>

## **2.3 Potential Risks and Benefits**

### **2.3.1 Potential Risks**

Survey and interview participation has minimal risk for the participants. Both are voluntary and participants may discontinue participation at any time. Patients and practitioners may not feel comfortable answering questions on the survey, and dental plan administrators may not feel comfortable answering questions during the telephone interview. Consequently, participants will have the option to skip any question. As with any study, there is a risk for loss of confidentiality. Appropriate precautions and procedures will be implemented to prevent this loss. These include the use of unique study codes for participants and password-protected computers for data storage. Compliance with all Institutional Review Board (IRB) regulations concerning data collection, data storage, and data destruction will be strictly observed. Data will only be accessible to research personnel and will be stored and coded according to guidelines set forth by the overseeing IRB.

### **2.3.2 Potential Benefits**

Study participants are not likely to experience direct benefit from participating in the study. Information gained from this research may provide valuable information about the feasibility of offering MRAs, counseling, and referrals in a range of dental practices.

## 3 OBJECTIVES

### 3.1 Study Objectives

#### 3.1.1 Primary Objective

The primary objective of this study is to describe dentist and hygienist attitudes and willingness towards conducting multi-risk assessments (MRAs) in dental offices, providing counseling, and making referrals for health risk behaviors and medical conditions identified through screening.

#### 3.1.2 Secondary Objectives

The secondary objectives of this study are to:

- Describe organizational and external factors that may influence dentist and hygienist attitudes and willingness towards conducting MRAs, providing counseling, and making referrals in dental practices,
- Describe dental patients' attitudes toward completing MRAs in dental practices and discussing their health risk behaviors with dentists and/or hygienists, and
- Examine dental payer perspectives about the feasibility of conducting MRAs in dental practices.

### 3.2 Study Outcome Measures

#### 3.2.1 Primary Outcomes

To address the primary objective, the Dental Practitioner and Practice Survey instruments (see *Appendix A*) will be used to assess the following primary outcome measures: (1) dentists' and hygienists' current MRA practice patterns including the number and type of health risks screened for during a dental visit; (2) practitioner perceived self-efficacy in conducting MRAs; (3) belief in effectiveness of MRAs; and (4) practitioner recommendations for conducting MRAs in their practices and providing counseling and making referrals based on those assessments. All data will be self-reported by consenting, participating dental practitioners and will focus on screening for the following risk behaviors and medical conditions: tobacco use; alcohol use; behaviors that may contribute to contracting HIV and other sexually transmitted infections; raising patient awareness about dental risks associated with the consumption of foods and beverages with high sugar content; risk factors for diabetes, hypertension, and heart disease, including asking about family history of the disease (s), and the presence of diabetes, hypertension, and heart disease.

#### 3.2.2 Secondary Outcomes

3.2.2.1. The following organizational and external factors will be ascertained from dental practitioners' survey responses and assessed for their influence upon dentist and hygienist attitudes and willingness towards conducting MRAs, providing counseling, and making referrals in dental practices:

- Organizational: (1) summary of dental practice characteristics (number of dentists, public/private, years in practice, number of hygienists); (2) capacity for the dental practice to change, as measured on the Change Process Capability Questionnaire, and (3) resources to sustain changes within the practice as measured by the Dentist and Hygienist MRA Practices and Adaptive Reserve Questionnaire.

- External: (1) dentist and hygienist reported availability of referral resources for identified problems, (2) payment strategies for dentists (e.g., capitation, fee-for-service, and other types); (3) claims submission procedures and processing times for payment to dental providers; and (4) dentist and hygienist scope of practice related to MRAs for the states in which they practice.

3.2.2.2. To describe patients' attitudes towards completing MRAs in dental practices and discussing their health risk behaviors with dental practitioners, the Dental Patient Questionnaire directed to dental patients will ascertain the following outcomes: (1) Patients' attitudes toward MRAs, counseling, and referrals at the time of a dental visit; and (2) patient variations in attitudes based on race/ethnicity, gender and age.

3.2.2.3. To describe dental payer perspectives about the feasibility of conducting MRAs in dental practices, representatives from dental payers will be interviewed to ascertain the following feasibility and acceptability outcomes: (1) dental payers' current reimbursement strategies related to MRAs, (2) their attitudes toward incorporating MRAs into dental practices, and (3) their perceived capacity to reimburse for MRAs.

#### **4 STUDY DESIGN**

We will seek dentist, hygienist, dental plan, and patient perspectives regarding utilization of MRAs in dental practices using a mixed methods strategy,<sup>30</sup> combining quantitative and qualitative methods. We will administer cross-sectional surveys to dental clinicians and their patients, and we will conduct in-depth interviews with dental plan directors.

**Dental Practitioner Survey:** Approximately 870 dentists and hygienists (all survey-eligible practitioners) in the SA region will be invited to participate in the Dental Practitioner Survey, which will be available in electronic and paper formats. Prior to survey recruitment, the number of dentists and hygienists in each dental office will be determined using location and practitioner IDs, and one practitioner per office will be invited to take the survey. If there is only one eligible practitioner (dentist or hygienist) in the office, the eligible practitioner will be invited to complete the survey. If an office has a dentist and hygienist who are eligible for survey participation, the invitation will be addressed to the dentist for completion. If a clinic has two eligible dentists, the invitation will be directed to one randomly selected dentist and will indicate that the survey and link are unique to that individual. If the office requests a paper survey, the office will be asked to have the eligible practitioner described above complete the survey. For those offices with two dentists, the paper survey will request that the randomly selected dentist complete the survey.

The Study Team and SA Region Study staff will identify approximately 30 practitioners who return completed surveys and are interested in and eligible to participate in the Dental Patient Survey portion of the study. The practitioners and/or office staff will invite adult patients who will be seen for a routine dental screening/check-up visit to participate in the study. A routine dental screening can include initial comprehensive examination, periodic examinations, recall/maintenance care or a routine hygiene appointment.

**Dental Patient Surveys:** Each participating practice (practitioners and/or office staff) will be asked to invite eligible patients to complete patient questionnaires before the dental screening/check-up visit and immediately after until approximately 30 patients per office (900 patients total) participate in the study. Participating practitioners will be asked to use a consecutive patient recruitment strategy, adapted to fit practice constraints among individual dentists, to control for selection bias. Patients will deposit their surveys into a sealed collection box at the office. After data collection is complete within a practice, the boxes will be returned to the University of Florida Data Coordinating Center (UF DCC) for data entry. Patient survey data collection is expected to take 3 to 4 months.

**Dental Plan Dental Director In-Depth Interviews:** The National Association of Dental Plans (NADP) has agreed to participate in the study by providing contact information for the dental directors of member plans. There are 70 NADP members; the study team will attempt to recruit approximately 20 dental plan directors for telephone in-depth interviews, with an emphasis on recruiting all of those from the largest plans. All interviews will be conducted within approximately 3 months after the dental directors are recruited.

**State Scope of Practice Documents:** The project coordinator will first conduct an online search for the Scope of Practice documents. For those states where the document is not available online, the project coordinator will contact the licensing authority for each SA Region state in the National Dental PBRN via letter, email, and/or telephone to request a copy of the dentist and

hygienist Scope of Practice documentation for that state. The project coordinator will review each document for any reference to health risk assessments. If the Scope of Practice documents are not clear about whether there are restrictions regarding health risk assessments in dental practices, the project coordinator will contact the licensing authority to seek clarification. All data from the state and information from the Scope of Practice document review will be recorded in a RedCap database, and Dr. Gewartowski will provide input regarding interpretation of scope of practice findings. Since this aspect of data collection does not involve human subjects, it will not be discussed elsewhere in the protocol.

### **STUDY SETTING**

The Study will be conducted in the South Atlantic Region of the National Dental Practice Based Research Network.

## 5 STUDY ENROLLMENT AND WITHDRAWAL

### 5.1 Inclusion Criteria

A dental practitioner (dentist and hygienist) participating in the Dental Practitioner Survey must meet all of the following criteria:

- Is enrolled in the SA Region of the National Dental PBRN as limited or full network member;
- Is licensed in the U.S. to treat patients, treats patients in the U.S. on a recurring basis and maintains an active practice address at which he or she can be contacted

A dental practitioner participating in the Dental Patient Survey component of the study must meet all of the following additional criteria:

- Is enrolled in the SA Region of the National Dental PBRN as full network member; and
- Has returned the completed Dental Practitioner Survey by the end of the open window for this component of the study.

A dental patient must meet all of the following criteria:

- Is 18 years or older
- Seen for a routine checkup or dental screening visit during survey administration

A dental plan dental director must meet all of the following criterion:

- Is a dental plan dental director from the National Association of Dental Plans

### 5.2 Strategies for Recruitment and Retention

**Dental Practitioner Survey:** Licensed dental practitioners who are members of the National Dental PBRN in the SA region and are survey-eligible will be invited to participate in the survey. Within the SA region, there are 870 practitioners (469 dentists and 401 hygienists). Based on previous National Dental PBRN surveys conducted in this network, we expect a dental practitioner participation rate of 60%. To optimize our response rates, we will follow National Dental PBRN recommendations for conducting cross-sectional dental practitioner surveys. We will strive for an 80% response rate and 698 completed surveys from dental practitioners.

An emailed or mailed (if no email address is available) invitation will be sent to all survey eligible participants in the SA region. The dental practitioners will be given three options: (1) complete the survey electronically, (2) request a paper copy, or (3) decline participation. The survey will be formatted so that it can be completed on a mobile device for participants choosing the online version.

One reminder email with the survey link and the options to request a written survey or to decline will be sent within 3 months of the initial email. SA Regional Coordinators (RCs) will contact non-responders to encourage survey participation

Using location and practitioner IDs, we are able to identify the number and type (e.g. dentist, hygienist) of practitioners at each office. The eligible practitioner in the office will be asked to complete the survey (dentist or hygienist). If an office has a dentist and hygienist who are eligible for survey participation, the invitation will be addressed to the dentist for completion. If a clinic has two eligible dentists, the invitation will be directed to one randomly selected dentist



and will indicate that the survey and link are unique to that individual. Dental practitioners will be remunerated \$75 after completing the survey.

For those dental practitioners requesting a paper survey, the University of Florida study team will mail a survey packet with instructions to them 60 days of receiving the request. SA Regional Coordinators (RCs) will contact non-responders to encourage survey participation. It is estimated that 20% of the dental practitioners will request a paper survey based on National Dental PBRN experience. If there is less than a 40% response rate, paper surveys may be sent as part of follow-up.

**Dental Patient Surveys:** We will identify approximately 30 dental practitioners from the SA Region who completed the practitioner survey and are willing and eligible to have their office participate in the Dental Patient Survey portion of the study. Specifically, following the procedure from the Ray et al.<sup>31</sup> study, each practice will be asked to invite patients who meet study inclusion/exclusion criteria to complete a survey immediately prior to and after the routine screening/check-up dental visit. Practices will be asked to maintain a log indicating the number of patients asked to complete the survey, the number declined and the number completed. The before and after visit surveys will be linked using a unique patient ID.

Practitioners will be asked to use a consecutive enrollment strategy for the targeted enrollment period of 12 weeks, which can be adapted to their practice workflow. For example, practices could elect to enroll consecutive eligible patients daily until the target number is reached or enroll consecutive eligible patients on certain days of the week. Practitioners will be asked to identify a recruitment schedule and adhere to that schedule. However, recruitment schedules may be adjusted with the consultation of the Regional Coordinator (RC).

Patient participants will be given a \$10 gift card as remuneration for survey completion. Practices will be remunerated a total of \$150 for their time in distributing all the patient surveys and \$5 for each survey that is collected.

**Dental Plan Dental Director:** There are 70 NADP members, with the 10 largest members covering 80% of individuals in the US who have dental insurance. Using contact information for dental directors provided by the NADP, we will attempt to recruit 20 dental directors for telephone in-depth interviews, with an emphasis on recruiting all of those from the largest plans. Based on Dr. Metch's experience with the NADP and our own experience in conducting in-depth interviews with dental plans, we expect an 80% participation rate.

## **5.3 Participant Withdrawal**

### **5.3.1 Reasons for Withdrawal**

Practitioners, dental plan directors and patients are free to withdraw from participation in the study at any time.

### **5.3.2 Handling of Practitioner and Patient Withdrawals**

Practitioners and dental plan directors who withdraw from the study prior to completion of the online survey or the in-depth interviews will not be replaced. We anticipate that practices selected to administer the patient survey will be able to do so successfully, but they will not be replaced if they fail to do so.

#### **5.4 Premature Termination or Suspension of Study**

This study may be suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party. If the study is prematurely terminated or suspended, the SPI will promptly inform the Institutional Review Board (IRB) and will provide the reason(s) for suspension or termination. Circumstances that may warrant termination include, but are not limited to:

- Insufficient adherence to protocol requirements.
- Data that is not sufficiently complete and/or evaluable.
- Determination of futility

## 6 STUDY SCHEDULE

### 6.1 Dental Practitioner Survey

- Eligible dentists and hygienists in the SA Region National Dental PBRN will be invited to complete the Dental Practitioner Survey, with a final reminder sent within three months after the initial mailing. If the response rate is less than 40%, a paper mailing may be used in follow-up.
- Agreement to enter the survey will include a waiver of documentation of informed consent per the National Dental PBRN Central IRB regulations with local context review conducted by the University of Florida (UF) IRB.

### 6.2 Practitioner Participation in Dental Patient Surveys

The Dental Patient Survey component of the study will proceed in the following stages on a rolling basis:

- 1) Practitioners who return completed surveys will be invited to participate in the patient survey component of the study to obtain a total of approximately 30 practitioners across all states in the SA Region;
- 2) Practitioners will complete activities to be deemed study ready;
- 3) Once practitioners are study ready, RCs will ensure practices are trained in the appropriate study procedures for patient survey data collection;
- 4) Practitioners will screen patients and invite eligible patients to participate in the survey study.

Once the RC has trained an enrolled office on study procedures, that practice should begin recruiting patients into the study immediately, or as soon as possible.

### 6.3 Patient Enrollment in Dental Patient Surveys

- Practice staff verify patient inclusion criteria;
- Agreement to enter the survey will include a waiver of documentation of informed consent per the National Dental PBRN Central IRB regulations.
- Patient completes pre-appointment survey;
- Patient completes post-appointment survey.

### 6.4 Dental Plan Interviews

- Study staff will identify and invite dental plan dental directors to participate in in-depth interviews;
- Verify inclusion criteria of dental plan dental directors;
- Verify and document consent according to regional IRB requirements;
- Complete in-depth interview

## 7 STUDY PROCEDURES/EVALUATIONS

### STUDY PROCEDURES

**Cognitive Testing:** The Dental Practitioner Survey (Dentist and Hygienist MRA Practices and Adaptive Reserve Questionnaire and Change Process Capability Questionnaire (CPCQ)) tools have undergone cognitive testing conducted by the study PI, using in-depth semi-structured interviews with 5 dentists who are similar to those who will be targeted in the survey. All the responses from the interviews were analyzed related to the categories of comprehension, retrieval, judgment, and response.<sup>31</sup> The structure and types of questions were similar to those used in other cognitive testing situations.<sup>32</sup> The instruments underwent minor revisions based on the cognitive testing results and recommendations from Dr. Gewartowski (study team member and consultant).

Specifically, modifications to the survey tools were made in response to the following comments:

- Participants indicated that the surveys were easy to understand and the questions are not controversial or difficult to answer.
- Participants requested the addition of questions asking if the dental practice would be willing to alter their physical layout to accommodate discussion of health risks and/or to modify its workflow.
- Participants requested that we ask if the screening by each category (e.g., hypertension, sleep apnea) is done for the initial visit, recall visits, all visits or not at all.
- Participants asked that the question about referral sources include both the dentist and members of the practice.
- For the CPCQ, the participants asked that the response choices of 1 (Strongly Disagree) through 5 (Strongly Agree) be represented as a continuum without labeling (1- Strongly Disagree, 2=Disagree etc.).

The Dental Patient Survey questions have also undergone cognitive testing, using the same procedures described for the Dental Practice Surveys. The study PI conducted the cognitive testing using in-depth semi-structured interviews with 5 patients who are similar to those who will be targeted in the survey. All of the responses from the interviews were analyzed related to the categories of comprehension, retrieval, judgment, and response.<sup>32</sup> The structure and types of questions were similar to those used in other cognitive testing situations.<sup>33</sup>

Specifically, the patient respondents made the following comments:

- They requested a colorful flyer explaining the study in addition to the instructions on the survey itself. They indicated that patients might be confused since dentists, in their experience, do not usually ask about health risks.
- The participants did not like the term “risk” and requested that a change be made to “health issues.” The participants saw the items as potential issues for their health but did not want to be perceived as having “risks”.
- The participants did not fully understand the association between HPV and HIV and oral health and what risk behaviors were associated with infection, and said some patients may have trouble answering those questions. The research team considered providing examples, but some participants said the examples could be viewed as intrusive. The research team decided to make no changes in response to this comment.

**Administration of the Dental Practitioner Survey (Dentist and Hygienist MRA Practices and Adaptive Reserve Questionnaire and CPCQ):** The online survey will be administered electronically via Qualtrics, the survey management system (SMS). Introductory emailed or mailed letters followed by individual emails with unique links to the online Dental Practitioner Survey will be generated through Qualtrics and sent to dental practitioners in the SA Region, explaining the purpose of the study and asking them to participate in the study. The dental practitioners also will be given the option to request a written survey packet and to decline to participate. For those dental participants who elect to complete the survey in the paper format, the UF project staff will enter the responses into a REDCap database. Westat will provide contact information for all practitioners who will be invited to participate.

The Dental Practitioner Survey includes two questionnaires. The first questionnaire – The Dental MRA Practices and Adaptive Reserve Questionnaire - is an adaption of a practice survey developed by Shenkman et al.<sup>34</sup> This survey was used in a National Institutes of Health (NIH)-funded study focused on deploying a health information technology (HIT)-enabled intervention to facilitate MRAs in medical primary care practices.<sup>2,34</sup> The questions were modified for this study to reflect dental practices (Appendix A) and then were further modified after the cognitive testing process. The questions are designed to assess: (1) dental practitioner self-efficacy (current practices, comfort with, beliefs about, and barriers toward the effectiveness of MRAs); and (2) the organizational structure available to support the implementation of new interventions such as the conduct of MRAs.

Adaptive reserve was originally conceptualized and measured as part of a national patient centered medical home (PCMH) demonstration project. Originally named the Clinician Staff Questionnaire, the Adaptive Reserve Questionnaire measures the following practice characteristics: communication style, leadership styles, learning culture, sense of safety to try new ideas, and approach to cultural diversity. A principal components analysis supported the five factor structure.<sup>35</sup>

The second questionnaire is the CPCQ (Appendix B). The CPCQ is designed to assess three domains: (1) the dental practices' history of change; (2) capacity for internal improvement and refinement; and (3) capacity to initiate and sustain change.<sup>17</sup> This survey is designed to provide an assessment of practices' ability to adopt new interventions and sustain them.

The CPCQ measures the following six categories within health care practice settings: organizational capabilities for change, infrastructure for implementation, implementation strategies, medical group characteristics, guideline characteristics, and external environment. The CPCQ was developed based on expert consensus to establish face and construct validity.<sup>36</sup> Follow-up studies related to implementing depression screening programs in medical practices show that the CPCQ total score and many of its subscores correlate relatively well with a medical group's priority for improving the quality of depression care and to support the change longitudinally.<sup>17</sup>

The CPCQ and the Adaptive Reserve Questionnaire are widely used in Agency for Health Care Research and Quality protocols focused on practice change in medical care settings.<sup>37</sup> These tools have not been used in dental practices, to our knowledge. However, they provide an opportunity to measure practice characteristics that have been associated with the ability to implement and sustain new approaches. While we likely will not have a sufficient sample size to

assess the psychometric properties of these instruments in dental practice settings, the administration of these tools will provide descriptive information about the practices.

**Administration of the Dental Patient Surveys:** The Dental Patient Surveys will be administered in dental offices via paper, prior to and after a dental appointment. The Dental Patient Surveys (Appendix C) comprise items adapted from a questionnaire developed by Shenkman et al., examining adolescent and young adult attitudes toward MRA screening,<sup>2</sup> and modified after cognitive interviewing. The Dental Patient Survey items were developed based on eight focus groups conducted with adolescents and young adults about questions they felt were important to be asked about their primary care visits. These questions have only been used in pilot studies and have not had additional testing beyond establishing construct validity through focus groups.

**Dental Plan Interviews:** The UF DCC study coordinator will send invitation letters to the dental plan dental directors, inviting them to participate in a 30 to 45-minute in-depth telephone interview. The UF DCC study coordinator will conduct follow-up calls within approximately 1 to 2 weeks of the initial mailing to schedule the interviews. Dr. Shenkman, or trained study staff, will follow-up within approximately 2 to 3 weeks after the initial mailing to personally discuss the project with those dental directors who do not respond to the DCC study coordinator. Dr. Shenkman has extensive experience conducting in-depth interviews with dental plan directors through ongoing quality of care assessments for the Medicaid and Children's Health Insurance Programs in Texas and Florida. Drs. Shenkman, Riley, or their trained designees, will conduct the in-depth interviews using a tool that has been used in Texas and Florida for over five years to conduct interviews with dental plan dental directors for Delta Dental, MCNA, and DentaQuest. The interview guide for these in-depth interviews is in Appendix D.

We will request permission to audio-record the interviews with dental plan directors. If a participant refuses, notes will be taken during the call. Audio-recordings will be transcribed verbatim with electronic transcripts uploaded to the Atlas ti,<sup>38</sup> qualitative data analysis and management software. Written notes also will be transcribed and uploaded to the software.

## 8 ASSESSMENT OF SAFETY

### 8.1 Specification of Safety Parameters

Safety monitoring for this study will focus on unanticipated problems (UP) involving risks to participants.

#### 8.1.1 Unanticipated Problems

The Office for Human Research Protections (OHRP) considers UPs involving risks to patients 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 patient population being studied;
- Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places patients or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

### 8.2 Reporting Procedures

Incidents or events that meet the OHRP criteria for UPs require the creation and completion of an UP report form. OHRP recommends that investigators include the following information when reporting an adverse event (AE), or any other incident, experience, or outcome as an UP to the IRB:

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

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

- Any other UP will be reported to the IRB and to NIDCR within 2 weeks of the SPI becoming aware of the problem.
- All UPs should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and OHRP within one month of the IRB's receipt of the report of the problem from the SPI.

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

- Product Safety Fax Line (US): 1-888-746-3293
- Product Safety Fax Line (International): 919-287-3998
- Product Safety Email: [rho\\_productsafety@rhoworld.com](mailto:rho_productsafety@rhoworld.com)

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

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



## **9 STUDY OVERSIGHT**

The GPI and SPI will be responsible for study oversight, including monitoring safety, ensuring that the study is conducted according to the protocol and ensuring data integrity. The SPI will review the data for safety concerns and data trends at regular intervals, and will promptly report to the IRB and NIDCR any UP, protocol deviation, or any other significant event that arises during the conduct of the study, per the IRB's reporting time-frame requirements. To ensure data integrity, the SPI and study team will adhere to quality management processes (see Section 13).

## **10 CLINICAL SITE MONITORING**

Clinical site monitoring will not occur for this study; however, data monitoring will occur. The SPI is responsible for study procedures and collecting data received through the surveys and in-depth interviews and will ensure that the quality and integrity of study data and data collection are maintained. Quality assurance/quality control activities associated with data collection and processing are outlined in Section 13.

NIDCR reserves the right to conduct independent audits as necessary.

## 11 STATISTICAL CONSIDERATIONS

### 11.1 Study Objectives

The primary objective of this study is to describe dentist and hygienist attitudes and willingness towards conducting multi-risk assessments (MRAs) in dental offices, providing counseling, and making referrals for health risk behaviors and medical conditions identified through screening.

The secondary objectives of this study are to: describe organizational and external factors that may influence dentist and hygienist attitudes and willingness towards conducting MRAs in dental practices; describe dental patients' attitudes toward completing MRAs in dental practices and discussing their health risk behaviors with dentists and/or hygienists; and examine dental payer recommendations about the feasibility of conducting MRAs in dental practices. Formal hypothesis testing will not be performed to achieve the study objectives.

### 11.2 Sample Size Considerations

With the main focus of this study to examine the feasibility of MRA implementation by dental practitioners and in a practice setting, the sample size was determined for feasibility purposes only.

**Number of Dental Patients:** Dental patients in this study will be sampled from the population of patients in SA region dental offices. Therefore, the required sample size is computed to provide a narrow enough 95% confidence interval (CI) for the outcomes (reported in percentages, e.g. percentage of dental patients willing to complete MRAs) ascertained in the patient survey. To be conservative, we use 50% for calculation because it requires the largest sample size for building CI. Considering a CI width of 0.07 ( $\pm 3.5\%$ ), we need a total of 810 patients based on the Clopper-Pearson method.<sup>39</sup> To ensure representativeness of our sample, we will recruit these patients from 30 dental offices in the SA region that are eligible to participate in survey administration. As a result, we will need to recruit approximately 30 patients from each of the 30 dental clinics ( $30 \times 30 = 900$ ).

### 11.3 Final Analysis Plan

#### Responders versus non-responders

The analysis will begin by linking the practitioner information from the Enrollment Questionnaire to the practitioners' responses on the surveys. Next, we will analyze the differences between responders and non-responders of the dental surveys initially using bivariate multivariable analyses such as chi-square tests and t-tests. We also will conduct logistic regression analyses to jointly examine the relationship of the predictor variables to the outcome of responding or not responding. The outcome variable will be "Responded" versus "Not Responded", and the predictor variables ideally will be age, gender, race, years since graduation, type of practice, setting of practice, demographic of practice, full or part-time practice, owner or associate/employee of practice, and any additional training after dental school. The predictor variables may need to be modified based on the information that Westat has available in its practitioner database. Predictor significance will be tested at 0.05 level.

For the dental plan directors' in-depth interviews, we will use appropriate statistical procedures (e.g. t-test, chi-square test) to test the differences between responders and non-responders in terms of the dental plan characteristics including the number of members served, profit/not-for-profit status, geographic areas served, and product lines offered (e.g., Medicaid, commercial).

The study team will not have any information about the patients to conduct an analysis of responders and non-responders. The study team will carefully describe the percentage of eligible patients who completed a survey using the logs that the practices keep.

There are several options to address missing data from respondents not fully completing the survey. For the dental survey participants, it is possible to follow-up with the practices to obtain the missing information. However, to protect privacy of the survey respondents, this is not a strategy that the research team is selecting. The patient surveys have no identifying information so it is not possible to follow up to obtain answers to missing responses. Because the dental plan directors interview is conducted as an in-depth interview via conference call, refusal to answer any questions will be documented but further analyses will not be conducted to address missingness.

The research team will use the following strategies for both the dental practitioner surveys and the patient survey. First an assessment of whether any missing items are missing at random (MAR) or missing not at random (MNAR). For example, if patient respondents consistently refuse to answer questions about their race and ethnicity, this would be MNAR. The research team expects that data will be MAR due to variations in responding. The imputation techniques will vary depending on whether the data is MAR or MNAR. However, in general, the research team will use multiple imputation in SAS. In multiple imputation, the SAS software takes advantage of correlations between responses. The software creates plausible values based on the correlations for the missing data and then averages the simulated datasets by incorporating random errors in the predictions.

**Primary Objective:** We will use descriptive statistics (frequencies and percentages) to summarize the responses from the dental practitioner surveys. In addition, we will build a logistic regression model to analyze practitioners' willingness to provide MRAs (ordinal response: the extent to which the dental practitioners report they would consider offering MRAs in their practices as asked in item 24) as predicted by current health risk screening practices, referral barriers reported, reimbursement challenges, capacity for change, and adaptive reserve. Practice characteristics (e.g., public, private; numbers of patients served) will serve as "demographic" control variables. We will build separate regression models for dentists and hygienists. Predictor significance will be tested at 0.05 level.

**Secondary Objectives:** For the first secondary objective, we will build a logistic regression model of dental practitioners' willingness to conduct MRA as a function of dental organizational (practice size, public/private, capacity for change, adaptive reserve); dental practitioner (belief in effectiveness of MRAs, current practice patterns, perceived self-efficacy), and external (reimbursement, referral options) factors. The dental survey responses will be grouped to reflect organizational, dental practitioner, and external factors. The importance of each factor influencing dental practitioners' attitudes will be tested at the 0.05 significance level.

For the second secondary objective related to the patient surveys, we will use descriptive statistics (frequencies and percentages) to summarize dental patients' demographic characteristics and their attitudes toward completing MRAs and discussing health risks behaviors with dental practitioners. We will build logistic regression models to analyze patients' willingness to complete MRAs and discuss health risk behaviors as predicted by gender, age, race/ethnicity, and the state within the National Dental PBRN SA Region. Separate models will be built focused on patient's willingness to complete MRAs using the responses for items: 2, 3, 4, 5, 6, and 7 from the Patient Questionnaire. Predictor significance will be tested at 0.05 level.

For the third secondary objective related to the dental plan administrator responses, descriptive statistics will be used to describe the organizational characteristics of the dental plans whose administrators participated in the in-depth interviews. The Atlas ti software will be used to analyze the qualitative data from the in-depth interviews. Using a grounded theory approach, four of the study co-investigators (Shenkman, Riley, Nelson, and Staras), each with differing academic backgrounds, will individually review transcripts and identify emergent themes and concepts.<sup>40</sup> The analysis team will meet, discuss repeating concepts and themes, and create a coding manual. Two members of the project team (Riley and Staras) will then individually conduct focused coding of each transcript. Weekly meetings will be held with the analysis team to discuss the assigned codes and to arrive at consensus with further discussion of themes that emerged after the more in-depth coding and analysis. This reflective and collaborative process aims to prevent biases of a single researcher.

For the scope of practice analyses, two investigators (Shenkman and Riley) will review the documents and identify any barriers for dentists or hygienists to conduct MRAs and provide follow-up counseling and referrals. Dr. Gewartwoski will review all reports from the qualitative and quantitative analyses and will make recommendations regarding the interpretation of the results.

Finally, the information obtained from the primary objective and the preceding secondary objectives will be used to determine the feasibility of conducting MRAs in dental practices. The entire team will review all results and prepare the information.

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## 12 SOURCE DOCUMENTS AND ACCESS TO SOURCE DATA/DOCUMENTS

Source data/documents will be maintained by the UF DCC for this study. Only study personnel, i.e., the SPI, NND and UF DCC staff, will have access to these data elements. All research documents will be stored on password-protected servers. Source data/documents and access for each data element will be as follows:

**Dental Practitioner Survey:** The Dental Practitioner Survey data will be collected electronically via Qualtrics, which allows for a link to the survey to be emailed directly to the practitioner from the Qualtrics interface. After the survey is submitted electronically, data will be available for review in Qualtrics. Dental practitioners also will be given an option to request a written survey packet. Data from the written surveys will be entered by the study staff into a RedCap database.

**Patient Log:** We will provide the offices with a paper log to track the number of patients approached to take the survey. Practices will be asked to record the patient IDs for all surveys. At the end of patient data collection, practices will mail the log along with the completed patient surveys back to the UF DCC. Study personnel will record the log information into the survey management system REDCap. Physical files will be kept in a secure, locked file at the SA Regional Administrative Site (RAS) or at the UF DCC.

**Patient Survey:** All patient surveys will be paper-based, collected during the patient's visit and stored in a secure lock-box in each office. After patient data collection is complete, all surveys and lock-boxes will be mailed to the UF DCC. After receiving the paper-based surveys, study personnel will enter responses into the survey management system REDCap. Physical files will be kept in a secure, locked file at the SA RAS or at the UF DCC.

**Dental Plan Interviews:** We will request permission to audio-record the Dental Plan in-depth interview calls. If allowed, the audio files will be saved on a password-protected, secure UF server and be transcribed verbatim with the electronic transcripts uploaded to the Atlas-ti or NVivo qualitative data analysis and management software. If permission to audio-record is not granted, detailed notes will be taken, transcribed and also uploaded to the Atlas ti or NVivo qualitative data analysis and management software.

### 13 QUALITY CONTROL AND QUALITY ASSURANCE

For the QA/QC activities associated with data collection and processing, the UF study team will ensure that automatic data quality checks are programmed into the SMS for the survey and will develop the processes related to the data manual review, discrepancy management, data verification and approval, and database audit.

The SPI will ensure that the electronic and paper surveys are being collected appropriately and confidentially and will ensure completeness of data collected. Conference calls with the Study Team (and relevant RCs) will be held at least monthly (more often if deemed necessary) during the survey and questionnaire data collection phase to monitor recruitment progress and data completeness and troubleshoot any problems that may arise.

**Dental Practitioner Survey:** The Dental Practitioner Surveys will be sent from the Qualtrics interface directly, and reminders will be sent automatically to all participants using Qualtrics. Instructions on survey completion will also be sent with the survey link. Electronic data will be available for review in Qualtrics after a survey is submitted. The study staff will enter the written survey data into a RedCap database. The study team will ensure that data fields in the Qualtrics and RedCap are checked for completeness and accuracy so that data entered into either system can be validated and data errors can be corrected. The UF DCC study coordinator will review the data and report any errors to the SPI.

**Patient Log:** The UF DCC study coordinator will review all patient logs and match the patient IDs to the completed patient surveys after they have been mailed with the lockboxes to the UF DCC. They will also record the number of patients approached, the number who refused and the number of completed surveys.

**Patient Survey:** After receiving the paper-based patient surveys, the UF DCC study coordinator will review all paper surveys for completion and accuracy and match the patient IDs to those listed on the log. The RC will enter all paper-based surveys into REDCap. After all surveys have been entered, one additional study personnel will review the paper-based surveys compared to the data in REDCap for errors. Any issues found will be discussed between the RC and additional study personnel. Unresolved errors will be submitted to the SPI for review and resolution.

**Dental Plan Interviews:** During the in-depth dental plan interviews, two audio-recorders will be used in case of failure. If audio-recording is not allowed, detailed notes will be taken by a study team member who will not be conducting the interviews. This will allow for full attention to be given to accuracy of the notes. After the audio or notes from the dental plan interviews have been transcribed and uploaded to the qualitative data analysis and management software, the UF DCC study coordinator will perform QC/QA checks on the data. They will ensure the transcription is correct based on the original source and that the data in the management software also matches the source data. After the UF DCC study coordinator finishes checking the transcription and uploaded data, an additional study team member will perform a secondary review to ensure accuracy of the transcribed and uploaded data. Any discrepancies found by either study team member will be reported to and resolved by the SPI.

Both REDCap and Qualtrics will ensure that all required data are collected per protocol requirements, and edit checks will be programmed into the web survey to correct data issues in

real time. Additionally, reports or tools will be developed to help monitor the data quality activities. The reports with the summary of the data completeness and accuracy will be made available to the GPI, study team, and NIDCR as requested.



## 14 ETHICS/PROTECTION OF HUMAN SUBJECTS

### 14.1 Ethical Standard

The GPI, SPI, and Co-Investigators will ensure that this study is conducted in full conformity with the principles set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, as drafted by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (April 18, 1979) and codified in 45 CFR Part 46.

### 14.2 Institutional Review Board

The National Dental PBRN Central IRB will review this protocol with local context review provided by the University of Florida Health Science Center Institutional Review Board (IRB-01). All materials submitted will be made available to the National Dental PBRN and the University of Florida IRB-01.

Approval of both the protocol and the consent form will be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the National Dental PBRN Central IRB and the University of Florida IRB-01 before the changes are implemented in the study.

### 14.3 Informed Consent Process

The informed consent process for each study component will be as follows:

**Dental Practitioner Survey:** A waiver of documentation of signed informed consent will be requested for the Dental Practitioner Surveys. Consistent with regulations outlined by the National Dental PBRN Central IRB and UF IRB, information about the study will be provided to eligible practitioners in an initial study invitation as well as on the entry page to the electronic survey. Completion of the survey will provide a record of tacit consent. To withdraw, practitioners can contact the study coordinator if they wish to no longer receive study reminders, or they can stop answering the survey questions at any time. They can also contact the study coordinator to withdraw after survey completion; the UF DCC study coordinator will remove their responses upon the practitioner's request.

**Patient Survey:** A waiver of documentation of signed informed consent will be requested for the Patient Survey. Consistent with regulations outlined by the National Dental PBRN Central IRB and UF IRB, information about the study will be provided at the beginning of the patient questionnaire. Dental practitioners or designated practice staff will be asked to review the study information with the patient. Any questions the patient has that cannot be answered by the dental practitioner or practice staff will be directed to the UF DCC study coordinator. The patient may contact the UF DCC study coordinator directly, or have the practice contact the coordinator on their behalf. Completion of the survey will provide a record of tacit consent. Patients can stop answering survey questions at any time in order to withdraw. They can also contact the study coordinator to withdraw after survey completion; the UF DCC study coordinator will remove their responses upon the patient's request.

**Dental Plan Interviews:** A waiver of documentation of signed informed consent will be requested for the in-depth Dental Plan interviews. Consistent with regulations outlined by the National Dental PBRN Central IRB and UF IRB, information about the study will be provided to

the Dental Plan Directors in an initial study invitation packet as well as the interview questions that will be asked. The UF DCC study coordinator will contact the dental plan director to schedule a convenient time for the interview. The dental director's agreement to start the interview at the scheduled time will be taken as tacit consent. To withdraw, dental plan directors can stop answering the interview questions at any time and inform the interviewer of their intention to withdraw during the interview. They can also contact the UF DCC study coordinator to withdraw after the interview; the UF DCC study coordinator will remove their responses upon the dental plan director's request.

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

Racial and ethnic minorities will be included in the study at least proportional to their composition in National Network dental practitioner membership and patient population. Individuals of any gender or racial/ethnic group may participate.

#### **14.5 Participant Confidentiality**

Practitioner and patient confidentiality is strictly held in trust by the study investigators, study staff, and the sponsor(s) and their agents. 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.

Only study personnel with CITI certification will have access to identified research data. Participants will be assigned a unique identification number, which will be used to maintain study records and organize data transcripts. A file linking participants' names and contact information with their unique identification number will be kept in a password-protected file on a password-protected server account of the SPI and will be destroyed after the study analysis is completed in accordance with IRB regulations. The study monitor or other authorized representatives of the sponsor may inspect all study documents and records required to be maintained by the study site.

## **15 DATA HANDLING AND RECORD KEEPING**

The study team is responsible for ensuring the accuracy and completeness of the data collected, and following the data collection and management procedures. Only study personnel (i.e., GPI, SPI, Co-I's, RCs, UF DCC personnel) will have access to the study data elements in the study database as described in Section 15.3 Types of Data. All study personnel will have completed the required training elements for human subjects research certification.

### **15.1 Data Management Responsibilities**

Data collection and accurate documentation are the responsibility of the study staff. The project staff has extensive experience with Qualtrics software for online survey data collection and REDCap for data management. The SPI will work closely with the project staff to ensure that the electronic and paper surveys and interview data are being collected appropriately, and confidentiality is being maintained according to the protocol specified procedures. Additionally, the Qualtrics software can be programmed to only accept variables, such as dates and numbers, which fall within a certain range and can be programmed to require a response to each question in order to prevent skipping. The SPI and study team will take responsibility for maintaining the PBRN contact list and enrollment questionnaire data, survey response data, and transcription data from the interviews. All data reported in the Qualtrics SMS will be checked by the study team for completeness and consistency. Dental practitioner written survey data and patient survey data and document review data pertaining to Scope of Practice will be entered into RedCap. While REDCap provides the capacity to program response limiters (to prevent impossible responses, reduce typos), study personnel will review data weekly to identify impossible values, outliers, and missing data.

Interview data will be transcribed and maintained in files with appropriate version control. The UF CC will be responsible for data coding and will maintain a file management and related documentation system to ensure data confidentiality and quality control. A protocol for text data coding will be developed in order to ensure data coding quality and consistency.

The data center in which the servers hosting RedCap, Qualtrics, NVivo and Atlas-ti software are housed has strict access control; only authorized core personnel may access the facility unescorted. Servers are protected by an enterprise firewall, which provides both application and port based security. The database server can only be accessed from the internal UF Health network.

### **15.2 Data Capture Methods**

Data capture methods will be via direct electronic data capture using Qualtrics for the Dental Practitioner Survey, paper-based data collection for the Patient Surveys, and audio-recording or note taking for the Dental Plan Director interviews. Data from the cognitive testing and in-depth Dental Plan Interviews will either be audio-recorded or detailed in notes, transcribed and uploaded to a qualitative data analysis and management software. Paper-based survey data from patients will be entered into REDCap.

### **15.3 Types of Data**

Data for the study consist of the following:

- Practitioner survey data
- Patient survey data

- Patient logs
- Dental Plan Director interview data

#### **15.4 Schedule and Content of Reports**

The UF Study Team will monitor practitioner survey responses during the practitioner survey data collection phase through submissions of patient logs to the UF DCC study coordinator. Reports to monitor enrollment of each study component will be produced by the SPI bi-monthly and upon request and will be provided to study team, GPI, RCs, and NIDCR for review until data collection is complete. The contents of the report will include a summary of practitioner respondents and non-respondents to date in the SA region. Regular monitoring of responses and tracking of response patterns will also be communicated to RCs to assist with their communication efforts.

#### **15.5 Study Records Retention**

Study records will be maintained for at least three years from the date that the grant federal financial report (FFR) is submitted to the National Institutes of Health (NIH) or longer as dictated by local IRB or state laws/regulations.

As outlined by IRB regulations, data will be destroyed in an appropriate and safe way after three years from study closure. The file connecting subjects' names with their unique identification number will be kept in a password-protected file by the SPI for a minimum of three years, in accordance with IRB regulations, before being securely erased.

#### **15.6 Protocol Deviations**

A protocol deviation (PD) is any noncompliance with the clinical study protocol or good clinical practice principles. The noncompliance may be on the part of the patient, the practitioner, or study staff. As a result of deviations, corrective actions may be developed by the study staff and should be implemented promptly. All deviations from the protocol must be addressed in study patient source documents and reported to NIDCR and the local IRB, according to their requirements.

Any PD that is reportable to an IRB must also be reported to NIDCR. NIDCR defers to the IRB for reporting time-frame requirements. Once a PD has been reported to an IRB, action must be taken to report the deviation to NIDCR. If the IRB overseeing the study protocol requires annual reporting of PDs to their IRB, that reporting frequency is acceptable to NIDCR.

## **16 PUBLICATION POLICY**

This study will comply with the [NIH Public Access Policy](#), which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive [PubMed Central](#) upon acceptance for publication. All study personnel are required to read in its entirety and agree to abide by the network's "Data Analysis, Publications, and Presentations Policies" document. The current version of this policy is always kept at the network's public web site at <http://nationaldentalpbrn.org/publication.php>.

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## **APPENDICES**

Appendix A: Dentist and Hygienist MRA Practices and Adaptive Reserve

Appendix B: Change Process Capability Questionnaire (CPCQ)

Appendix C: Dental Patient Survey

Appendix D: Dental Plan Dental Director In-Depth Interview Guide

## **APPENDIX A: Dentist and Hygienist MRA Practices and Adaptive Reserve**

The purpose of this study is to characterize dental practitioners', dental payers', and patients' attitudes about conducting/participating in MRAs during dental visits; and providing/receiving follow-up counseling about and referrals for identified risks. Researchers at the University of Florida are conducting this NIH-NIDCR funded research.

***Informed Consent: Your completion of this survey is voluntary and should take approximately 10-20 minutes. All names you provide will be replaced with unique numbers to protect confidentiality. You do not have to answer any questions that you are uncomfortable answering.***

***You will be compensated for your participation. At the end of the survey, you will be asked if you would like to receive \$50 for completing this survey. At the conclusion of the survey you will be asked to verify your payment preferences for completion of the survey.***

***This research will not directly benefit you. The alternative is to not participate in the study. We hope that the results of this research will be useful to the dental community.***

***Your response is confidential. All data will be reported in the aggregate only. Data will be maintained only by unique code number, not by name, and you will not be identified in the results. All data will be used for scientific purposes only.***

***To make sure that this research is being carried out in the proper way, the UAB Office of the IRB (OIRB) may review study records. The Office of Human Research Protections may also look at study records. The sponsor of this study, NIH has the right to review study records as well. Your data will be stored in Westat in Rockville, Maryland and University of Florida, Gainesville, FL. If you have any questions about your rights as a research subject, you may contact the OIRB at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.***

Thank you for agreeing to participate in this survey.

Oral health is influenced by many factors including health risk behaviors such as tobacco use, alcohol use, and intake of sugary beverages. Health risk behaviors are often co-occurring with individuals engaging in more than one risk. In addition, health risk behaviors can contribute to the development and exacerbation of chronic medical conditions. For example, tobacco and alcohol use contribute to an increased risk for a range of physical and oral health problems including hypertension and cancer.

Dental visits for routine check-ups and screenings may provide the opportunity to comprehensively assess patients' health risks and to make referrals to address those risks; potentially improving both oral and physical health.

We are interested in learning more about the extent to which you comprehensively assess the patients in your practice for health risk behaviors, including tobacco and alcohol use, and for a family history or presence of chronic physical conditions. Assessments focused on more than one health risk are often called Multiple Risk Assessments.

We are also interested in learning more about the barriers you face in comprehensively assessing dental patients' health risk behaviors. This questionnaire also includes items about how your practice is organized and the strategies you use when you want to implement a new intervention.

Please choose from the following:

- I want to complete this survey electronically.”  
(please click on this link to complete the survey – insert link here)
- I want to complete this survey, but please mail me a paper version. A survey packet will be sent to you to complete within three business days.
- I do not want to participate in this survey. [*branching to...*]
  - The survey content does not apply to my practice. Please do not contact me further about this particular study.
  - I am not interested in participating, although this survey content does apply to my practice. Please do not contact me further about this particular study.

**For the purpose of this survey, please indicate the appropriate response for your current practice within the past 6 months. All questions refer to patients seen for a routine check-up and dental cleaning.**

## Section 1: Multiple Risk Assessment Practices

- Thinking about routine check-up and dental screening visits, for what *percentage* of your patients do you assess more than one health risk behavior that could affect both physical and oral health? Examples include: tobacco use, e-cigarette use, alcohol use, sexually transmitted infections (such as human immunodeficiency virus (HIV), human papillomavirus (HPV), herpes simplex virus (HSV)), and other health risks?

\_\_\_\_\_ %

**The questions below refer to routine checkup and dental screening visits. The questions also address any mode of administration to your patients (e.g., written questionnaires, verbal questions, both). Thinking about routine check-up and dental screening visits only...**

- ... how often do you ask your patients about their use of tobacco?

Never	Rarely	Occasionally	Usually	Always

- ... how often do you ask your patients about their use of e-cigarettes?

Never	Rarely	Occasionally	Usually	Always

- ...for your patients who use tobacco, do you discuss the oral health risks associated with tobacco use, such as risk of developing head and neck cancer?

Never	Rarely	Occasionally	Usually	Always

- ... for your patients who use tobacco, do you provide recommendations to them about nicotine replacement therapy?

Never	Rarely	Occasionally	Usually	Always

- ... for your patients who use tobacco, do you provide recommendations to them about non-medical tobacco cessation strategies? Examples include the use of quit lines, an online quit program or face-to-face classes?

Never	Rarely	Occasionally	Usually	Always

7. ... how often do you ask your patients about their use of alcohol?

Never	Rarely	Occasionally	Usually	Always

8. ... if you identify that a patient is abusing alcohol, how often do you discuss the risks that excess alcohol use poses for their oral health?

Never	Rarely	Occasionally	Usually	Always

9. ... how often do you ask your patients about risky behaviors, such as unprotected or oral sex, that may contribute to the development of sexually transmitted infections (such as HIV, HPV, and HSV)?

Never	Rarely	Occasionally	Usually	Always

10. ... if you identify that a patient is engaging in risky behavior that may contribute to the development of sexually transmitted infections, such as unprotected or oral sex, how often do you discuss these risks with the patient?

Never	Rarely	Occasionally	Usually	Always

12.... how often do you ask your patients about their consumption of foods that are high in sugar?

Never	Rarely	Occasionally	Usually	Always

13.... how often do you ask your patients about their consumption of beverages that are high in sugar?

Never	Rarely	Occasionally	Usually	Always

14.... how often do you ask patients about their level of physical activity?

Never	Rarely	Occasionally	Usually	Always

15.... how often do you ask your patients about their weight?

Never	Rarely	Occasionally	Usually	Always

16. Who routinely conducts health risk assessments in your office?

We do not conduct health risk assessments

- The dentists
- The hygienist
- Both the dentist and hygienist

## Section 2: Chronic Condition Screening Practices

The questions below refer to routine checkup and dental screening visits. The questions also address any mode of administration to your patients (e.g., written questionnaires, verbal questions, both).

Thinking about routine check-up and dental screening visits only...

1. ... how often do you ask your patients about whether they have a **family history** of?

	Never	Rarely	Occasionally	Usually	Always
Diabetes					
Hypertension					
Heart Disease					
Obesity					

- 2... how often do you ask your patients about whether **they have**?

	Never	Rarely	Occasionally	Usually	Always
Diabetes					
Hypertension					
Heart Disease					
Reflux or GERD					
Sleep problems or sleep apnea					
Obesity					

3. During routine check-up and screening visits, for what percentage of your patients do you...

*Please do not leave any blank. If you do not provide the particular item, please check (✓) "do not screen for this":*

	Percentages					
	I do not screen for this	Less than 25%	25% to 50%	51% to 75%	76% to 90%	Greater than 90%
Take blood pressure readings						
Ask the patient his/her height and weight						
Conduct HIV testing						
Offer blood glucose screening						
Offer other health screening tests: Name _____						
Offer other health screening tests: Name _____						
Offer other health screening tests: Name _____						

4. Who, in your office, routinely asks patients about a **family history** of chronic health conditions?

- We do not routinely ask about a family history of chronic conditions
- The dentists
- The hygienist
- Both the dentist and hygienist

5. Who, in your office, routinely asks patients if **they have** chronic health conditions?

- We do not routinely ask about if the patient has chronic conditions
- The dentists
- The hygienist
- Both the dentist and hygienist



6. At which visit are the following chronic condition assessments conducted?

*Check (✓) one for each of the following listed risk behaviors or health conditions:*

	Initial Visit	Recall Visit	All Visits	I Do Not Offer This
Blood pressure				
Weight				
HIV testing				
Blood glucose screening				
Diabetes				
Hypertension				
Heart disease				
Reflux or GERD				
Sleep problems or sleep apnea				

### Section 3: Knowledge Levels Related to Assessment and Screening

1. How knowledgeable do you think you or members of your practice are about referral sources (e.g., physician primary care providers, patient education classes, and/or individual counseling) for the following?

*Check (✓) one for each of the following listed risk behaviors or health conditions:*

	Not at All	Not Very	Moderately	Very
Tobacco Use				
Alcohol Use				
Other Substance Use				
STI Risks				
Diabetes				
Hypertension				
Heart Disease				
Reflux or GERD				
Sleep Problems or Sleep Apnea				
Obesity				
Nutritional Counseling				

## Section 4: Referral Practices for Identified Risks

- For patients where you have identified a health risk and/or health condition, how often do you refer your patients to resources (e.g., physician primary care providers, patient education classes, and/or individual counseling) for the following?

<b>How often do you refer your patients for each of the following behaviors/conditions? Check one response for each behavior/condition.</b>						
	<b>Percentages</b>					
	I do not screen for this	Less than 25%	25% to 50%	51% to 75%	75% to 90%	>90%
<b>Tobacco Use</b>						
<b>Alcohol Use</b>						
<b>Other Substance Use</b>						
<b>STI Risks</b>						
<b>Diabetes</b>						
<b>Hypertension</b>						
<b>Heart Disease</b>						
<b>Reflux or GERD</b>						
<b>Sleep Problems or Sleep Apnea</b>						
<b>Obesity</b>						
<b>Nutritional Counseling</b>						

- Do you have a specific primary care provider to whom you can refer your patients when you identify a health risk?
  - I typically refer the patient to his/her primary care provider if one is available
  - I have a primary care provider or providers I can refer to if the patient does not have one
  - I do not have any specific primary care provider or providers I can refer to if the patient does not have one
  
- How often do you follow-up with patients to determine if they kept any referrals that you recommended to them?
  - Always
  - Usually
  - Occasionally
  - Rarely
  - Never
  - Don't Know

## Section 5: Barriers

- Overall, what barriers do you face in conducting multi-health risk assessments in your practice (e.g., comprehensively assessing for multiple health risks during a dental visit including: tobacco use, alcohol use, risky sexual behaviors)?

Check (✓) one for each of the following listed risk behaviors or health conditions:

	Never	Rarely	Occasionally	Usually	Always
Lack of time					
Excessive paperwork to obtain reimbursement					
Lack of reimbursement					
Not comfortable with Multi-Risk screening					
Office set-up does not allow for private discussions					
My patients would be uncomfortable with the screening					
I do not have sufficient staff to conduct the screening					
I do not have data collection tools to gather the information from my patients					
I do not have referral sources if I identify health risks					
Conducting MRAs is beyond my scope of practice					
Other: Name _____					
Other: Name _____					

- Do you feel that you would need to modify the physical layout of your office to screen for and discuss health risks with your patients?
  - Yes
  - No
  - Don't Know
- Do you feel that you would need to modify the workflow in your practice to screen for and discuss health risks with your patients?
  - Yes
  - No
  - Don't Know

## Section 6: Attitudes

1. To what extent do you agree with each of the following statements?

*Check (✓) one for each of the following statements:*

	Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree
Comprehensive Health Risk assessments are important to offer in dental practices					
Comprehensive Health Risk assessments are better done in physicians' practices than in dental practices					
Comprehensive Health Risk assessments in <u>physician</u> practices can help prevent or reduce morbidity					
Comprehensive Health Risk assessments in <u>dental</u> practices can help prevent or reduce morbidity					
I would consider offering comprehensive Health Risk assessments in my dental practice					
Staff at all levels of this office openly talk about what is and isn't working					
After trying something new, we take time in our practice to think about how it worked					
People in this practice operate as a real team					

## Section 7: Open-Ended Questions

Please provide additional feedback below:

1. Do you think that multi-risk health assessments should be part of routine screening in dental practices? Why, Why Not?
2. Do you think that patients would benefit from screening and counseling for health risks in dental practices? Why? Why not?
3. Do you think establishing referral relationships with primary care physicians would be helpful for the early identification of and referral for identified health risks?
4. Do you think drugstore screening tests, such as glucose testing, could be helpful to your patients if they do not want a physician referral? Why/why not?
5. What changes, if any, would you like to see in dental practices to promote early detection and screening of health risks?

## Section 8: Practice Structure

1. Approximately how often do the dentists and staff at your practice site hold meetings to discuss the practice site's performance on:

*Check (✓) one for each of the following listed meeting topics:*

	Never	Annually	Quarterly	Monthly	More often than Monthly
Quality of dental care?					
Patient satisfaction ratings?					
Dentist or staff satisfaction?					
Dentist Productivity?					
Staff Productivity?					
Utilization or costs of care?					

2. Does your practice monitor the dental practitioner(s) personal performance on:

*Check (✓) one for each of the following listed items:*

	Yes	No	Don't Know
Dental quality of care?			
Patient satisfaction ratings? (e.g., patient experience surveys)			
Productivity? (e.g., patient volume, procedure volume)			
Utilization or costs of care?			

3. Does your practice monitor the staff members' personal performance on:

*Check (✓) one for each of the following listed items:*

	Yes	No	Don't Know
Dental quality of care?			
Patient satisfaction ratings? (e.g., patient experience surveys)			
Productivity? (e.g., patient volume, procedure volume)			
Utilization or costs of care?			

4. Do the practitioners at your practice site use planned communications (e.g., letters, phone calls, text messages) to contact patients who are due for dental visits?

- Yes
- No
- Don't Know

5. Does your practice site have:

*Check (✓) one for each of the following listed items:*

	Yes	No	Don't Know
<b>Agreements with community service agencies (e.g., health departments) to enhance services for any of your patients?</b>			
<b>A referral system for linking any of your patients to physician primary care providers?</b>			

6. Does your practice use computer-based dental records (as opposed to paper dental records) to manage clinical/patient data?

- Yes
- No

7. If yes, what is the name of the computer-based system that you use to manage dental clinical/patient data?

Thank you for completing the survey. As a thank you for your time, we would like to send a pre-paid gift card.

1. Would you like us to send you a \$50.00 electronic pre-paid payment card as a thank you for completing this survey? [remuneration]

- Yes, please send compensation
- No

2. If yes, please provide the best email address for receiving the gift card

## Appendix B: Change Process Capability Questionnaire (CPCQ)

The purpose of this study is to characterize dental practitioners', dental payers', and patients' attitudes about conducting/participating in MRAs during dental visits; and providing/receiving follow-up counseling about and referrals for identified risks. Researchers at the University of Florida are conducting this NIH-NIDCR funded research.

***Informed Consent:*** *Your completion of this survey is voluntary and should take approximately 5-10 minutes. All names you provide will be replaced with unique numbers to protect confidentiality. You do not have to answer any questions that you are uncomfortable answering.*

***You will be compensated for your participation. At the end of the survey, you will be asked if you would like to receive \$25 for completing the survey. At the conclusion of the survey you will be asked to verify your payment preferences for completion of the survey.***

***This research will not directly benefit you. The alternative is to not participate in the study. We hope that the results of this research will be useful to the dental community.***

***Your response is confidential. All data will be reported in the aggregate only. Data will be maintained only by unique code number, not by name, and you will not be identified in the results. All data will be used for scientific purposes only.***

***To make sure that this research is being carried out in the proper way, the UAB Office of the IRB (OIRB) may review study records. The Office of Human Research Protections may also look at study records. The sponsor of this study, NIH has the right to review study records as well. Your data will be stored in Westat in Rockville, Maryland and University of Florida, Gainesville, FL. If you have any questions about your rights as a research subject, you may contact the OIRB at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.***



How would you describe the current status of and attitudes toward quality improvement in your dental practice?

*On a scale of 1 to 5, 1 is strongly disagree and 5 is strongly agree.*

We have greatly improved the quality of care within the past 6 months	1	2	3	4	5	N/A
We choose new processes of care that are more advantageous than the old for everyone involved (patients, dental practitioners, and our entire group/clinic)	1	2	3	4	5	N/A
Our resources (personnel, time, financial) are too tightly limited to improve care quality now	1	2	3	4	5	N/A
The dental practitioners and staff in our practice have a shared vision about how we define quality of dental care	1	2	3	4	5	N/A
The dental practitioners in our practice adhere to practice policies	1	2	3	4	5	N/A
Our dental practice has well-developed administrative structures and processes in place to create change	1	2	3	4	5	N/A
Our dental practice is undergoing considerable stress as the result of internal changes	1	2	3	4	5	N/A
The working environment in our dental practice is collaborative and cohesive, with a shared purpose, cooperation, and willingness to contribute to the common good	1	2	3	4	5	N/A
Our dental practice has a well-defined quality improvement process for designing and introducing changes in the quality of care	1	2	3	4	5	N/A

Our dental practice has used the following strategies in the past 6 months to implement improved care quality:

*On a scale of 1 to 5, 1 is strongly disagree and 5 is strongly agree*

Provided information and skills-training for office staff	1	2	3	4	5	N/A
Used opinion leaders or role modeling to encourage change	1	2	3	4	5	N/A
Changed or created systems in the practice that made it easier to provide high quality care	1	2	3	4	5	N/A
Removed or reduced barriers to better quality of care	1	2	3	4	5	N/A
Organized people into teams focused on accomplishing the change process for improved care	1	2	3	4	5	N/A
Delegated to non-dentists the responsibility to carry out aspects of care that do not have to be carried out by dentists	1	2	3	4	5	N/A
Provided those who are charged with implementing improved care the power to authorize and make the desired changes	1	2	3	4	5	N/A
Used periodic measurement of health care quality to determine the effects of a new intervention	1	2	3	4	5	N/A
Developed reports that documented the measurements of individual or practice performance	1	2	3	4	5	N/A
Set performance quality goals and benchmarking rates at least yearly	1	2	3	4	5	N/A
Customized the implementation of any care changes to the practice site	1	2	3	4	5	N/A
Deliberately designed care improvements so as to make dentist participation less work than before	1	2	3	4	5	N/A
Deliberately designed care improvements to make the care process more beneficial to the patient	1	2	3	4	5	N/A

Thank you for completing the survey. As a thank you for your time, we would like to send a pre-paid gift card.

1. Would you like us to send you a \$25.00 electronic pre-paid payment card as a thank you for completing this survey? [remuneration]

Yes, please send compensation

No

2. If yes, please provide the best email address for receiving the gift card

## Appendix C: Dental Patient Survey

\*This survey will be administered to only those who are scheduled for a routine dental screening visit. Part 1 will be completed while waiting to be seen, with part 2 completed after the visit. Before visit and after visit surveys will be linked using a unique patient ID created from the Dental practitioner's location and practitioner ID, patient visit order and either a 1 to indicate the before visit or 2 for after visit.

### Part 1: Administered While in Waiting Room Pre-Visit

#### MRA Pre-visit Survey

<Survey # >

Please answer the following questions:

1. Do you now smoke cigarettes, cigars, or use smokeless tobacco?  
 Yes  
 No
2. Would you be comfortable discussing tobacco use with your dentist or hygienist?  
 Yes  
 No  
 I do not use tobacco
3. Would you be comfortable discussing alcohol use with your dentist or hygienist and how alcohol use may affect your oral health?  
 Yes  
 No  
 I do not use alcohol
4. Would you be comfortable discussing your intake of sugar sweetened beverages and how your beverage choices may affect your oral health? Sugar sweetened beverages are beverages such as soft drinks/sodas, fruit drinks, sports drinks, tea and coffee drinks, energy drinks, and sweetened milk or milk alternatives.  
 Yes  
 No
5. If applicable, would you be comfortable discussing with your dentist or hygienist issues that you may have related to *Human Immunodeficiency Virus* (HIV) and how this disease may affect your oral health?  
 Yes  
 No  
 I do not have any issues related to HIV

6. If applicable, would you be comfortable discussing with your dentist or hygienist issues that you may have related to *Human Papillomavirus* (HPV) and how this disease may affect your oral health?

- Yes
- No
- I do not have any issues related to HPV

7. Would you be comfortable discussing with your dentist or hygienist any medical conditions, such as diabetes, high blood pressure, or heart disease?

- Yes
- No
- I do not have any medical conditions

8. If you indicated that you are not comfortable in discussing one or more health issues with your dentist or hygienist, can you tell us why not?

9. Would you be willing to pay for a health issue assessment in your dentist's office?

- Yes
- No
- Don't Know

10. In the last 12 months, did you make any appointments for a check-up or routine care at a doctor's office or clinic?

- Yes
- No
- Don't Know

11. Approximately, when did you last see your primary medical care provider or clinic for a check-up or routine care?

I have not been to the doctor/clinic in the last 12 months

I have been to the doctor/clinic and the approximate date was:

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	201	<input type="text"/>
----------------------	----------------------	---	----------------------	----------------------	---	-----	----------------------

Month

Day

Year

Just a few more questions

12. Today's Date:  /  /

Month

Day

13. Your gender:

- Male
- Female

14. How old are you?   years old

15. Your ethnicity:

- Hispanic or Latino
- Not Hispanic or Latino
- I don't know
- Decline to answer
- Other: \_\_\_\_\_

16. Your race (Check all that apply):

- White
- Black or African American
- Asian
- American Indian or Alaska Native
- Native Hawaiian or Other Pacific Islander
- I don't know
- Decline to answer
- Other: \_\_\_\_\_

17. Your **dental** insurance type or third party coverage for any type of dental care (Check all that apply):

- No dental insurance coverage
- Private insurance (e.g., employer sponsored, commercial, HMO, etc.)
- Public/government insurance (Medicaid, military or veterans benefit, etc.)
- Other (please specify): \_\_\_\_\_
- Don't know

18. Indicate your highest level of education:

- Less than a high school diploma
- High school graduate (including equivalency, GED, etc.)
- Some college or Associate Degree
- Bachelor's degree
- Graduate degree (including Master's)
- Decline to Answer

19. ZIP code where you live:

Thank you for agreeing to participate in this survey. **Remember to do the post-visit survey at the end of your appointment.**

## Part 2: Administered Post-Visit

### MRA Post-visit Survey

<Survey #>

We are interested in learning if the health issues that concern you were discussed with your dentist or your dental hygienist during today's visit. Health issues include things like: tobacco use, alcohol use, and intake of sugar sweetened beverages. Health issues can also mean a medical condition like diabetes or heart disease.

#### **During your dental visit today...**

1. ... did anyone ask you if you smoke cigarettes, cigars, or use smokeless tobacco?  
 Yes  
 No
2. ... did anyone advise you to quit tobacco?  
 Yes  
 No
3. ... did anyone ask you if you drink alcohol?  
 Yes  
 No
4. ... did anyone discuss your nutrition with you such as your intake of sugar sweetened beverages?  
 Yes  
 No
5. ... did anyone discuss with you sexual behaviors, such as unprotected or oral sex, which might increase issues with diseases like HIV?  
 Yes  
 No
6. ... did anyone ask you about any existing medical conditions you may have such as diabetes, high blood pressure, heart disease?  
 Yes  
 No

Thank you for completing the surveys.

**Please place both before visit and after visit surveys in the locked box provided for the study.**

As a thank you for your time, we would like to give you a \$10 pre-paid gift card. **Please collect your gift card from the office before you leave.**

## Appendix D: Dental Plan Dental Director In-Depth Interview Guide

***Informed Consent:*** Your completion of this survey is voluntary and should take approximately 30-45 minutes. All names you provide will be replaced with unique numbers to protect confidentiality. You do not have to answer any questions that you are uncomfortable answering.

***You will not be compensated for your participation.***

***This research will not directly benefit you. The alternative is to not participate in the study. However, we hope that the results of this research will be useful to the dental community.***

***Your response is confidential. All data will be reported in the aggregate only. Data will be maintained only by unique code number, not by name, and you will not be identified in the results. Before the interview, we will ask you if we can audio-record the interview. You can decline and notes will be taken instead. If you agree, the audio recording will be transcribed following the interview and destroyed. All data will be used for scientific purposes only.***

***To make sure that this research is being carried out in the proper way, the UAB Office of the IRB (OIRB) may review study records. The Office of Human Research Protections may also look at study records. The sponsor of this study, NIH has the right to review study records as well. Your data will be stored in Westat in Rockville, Maryland and University of Florida, Gainesville, FL. If you have any questions about your rights as a research subject, you may contact the OIRB at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.***

1. When did your dental health plan begin coverage? Please provide dates for commercial, Medicaid, and CHIP coverage separately.

	Began coverage on:											
<b>Commercial coverage</b>	M	M	/	D	D	/	Y	Y	Y	Y		
<b>Medicaid coverage</b>	M	M	/	D	D	/	Y	Y	Y	Y		
<b>CHIP coverage</b>	M	M	/	D	D	/	Y	Y	Y	Y		

2. Are you affiliated with a university or hospital system?

Yes (**go to A**)



No (go to 3)

A. Name of affiliated organization:

[TEXT]
--------

Date affiliation began:

M	M	/	D	D	/	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---	---

1) Please provide the number of states in which your dental plan operates.

[NUMBER]
----------

2) Does your plan require practitioners to screen for the following health risks during any type of dental visits?

	Yes	No
Tobacco use	<input type="checkbox"/>	<input type="checkbox"/>
Alcohol use	<input type="checkbox"/>	<input type="checkbox"/>
Other substance use	<input type="checkbox"/>	<input type="checkbox"/>
Risky Sexual Behaviors (such as unprotected or oral sex)	<input type="checkbox"/>	<input type="checkbox"/>
Chronic conditions such as diabetes, hypertension, and others	<input type="checkbox"/>	<input type="checkbox"/>

3) Does your dental plan require dentists to screen for oral cancer as part of routine examinations?

- Yes
- No

4) Do you include time for screening for and discussing health risks with patients in your rate setting calculations?

- Yes
- No

5) Do you reimburse dental practitioners for

	Yes	No
For in Network Practitioners only	<input type="checkbox"/>	<input type="checkbox"/>
Any Dental Practitioners	<input type="checkbox"/>	<input type="checkbox"/>

Taking blood pressure readings	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Conducting HIV testing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Performing blood glucose screening	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other health screening tests: Name_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other health screening tests: Name_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other health screening tests: Name_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- 6) Do you think that multi-risk health assessments should be part of routine screening in dental practices? Why, Why Not
- 7) Do you think patients would find multi-risk health assessments acceptable in dental practices? Why? Why not?
- 8) Would you be supportive of dental practitioners in your network conducting multi-risk health assessments? Why? Why Not?
- 9) Would your dental plan reimburse dental practitioners for conducting multi-risk health assessments? Why? Why Not?
- 10) Do you think establishing better bi-directional referral relationships with physician PCPs would be helpful for the early identification of and referral for identified health risks?
- 11) What changes, if any, would you like to see in dental practices to promote early detection and screening of health risks?