**Mental Health Screening and Referral to Treatment in Dental Practices (MSDP): A Pilot Study**

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STATEMENT OF COMPLIANCE

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

SIGNATURE PAGE

The signature below constitutes the approval of this protocol and the attachments and provides the necessary assurances that this 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 US federal regulations and ICH guidelines.

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LIST OF ABBREVIATIONS

|  |  |
| --- | --- |
| AE | Adverse Event/Adverse Experience |
| BoP | Bleeding on Probing |
| CFR | Code of Federal Regulations |
| CIOMS | Council for International Organizations of Medical Sciences |
| CRF | Case Report Form |
| CROMS | Clinical Research Operations and Management Support |
| CSI | Clinical Site Investigator |
| CSOC | Clinical Study Oversight Committee |
| DCC | Data Coordinating Center |
| Dental Office Personnel | Dentist, Dental Hygienist, Dental Assistant, and Office Staff |
| DHHS | Department of Health and Human Services |
| FFR | Federal Financial Report |
| FWA | Federalwide Assurance |
| GCP | Good Clinical Practice |
| HIPAA | Health Insurance Portability and Accountability Act |
| ICF | Informed Consent Form |
| ICH | International Council for Harmonisation |
| ICMJE | International Committee of Medical Journal Editors |
| IRB | Institutional Review Board |
| MOP | Manual of Procedures |
| N | Number (typically refers to participants) |
| NC | Node Coordinator |
| NIDCR | National Institute of Dental and Craniofacial Research, NIH, DHHS |
| NIH | National Institutes of Health |
| OCTOM | Office of Clinical Trials Operations and Management, NIDCR, NIH |
| OHRP | Office for Human Research Protections |
| OHRQoL | Oral Health-Related Quality of Life |
| OHSR | Office of Human Subjects Research |
| PBRN | National Dental Practice Based Research Network |
| PD | Protocol Deviation |
| PI | Principal Investigator |
| PO | Program Official, NIDCR, NIH |
| PS | Project Scientist, NIDCR, NIH |
| QA | Quality Assurance |
| QC | Quality Control |
| SAE | Serious Adverse Event/Serious Adverse Experience |
| SOP | Standard Operating Procedure |
| UP | Unanticipated Problem |
| US | United States |

PROTOCOL SUMMARY

|  |  |
| --- | --- |
| **Title:** | Mental Health Screening and Referral to Treatment in Dental Practices (MSDP): A Pilot Study |
| **Précis:** | In 2017, it was estimated that approximately 46.6 million adults, or approximately 19% of the adult population, had a mental health illness. Unlike primary medical services, where screening for mental health concerns is standard practice, dental offices rarely perform mental health screenings as part of routine dental care. The MSDP pilot study will use quantitative methods to evaluate the patient and dental office perceptions of feasibility on integrating mental health screening and referral to treatment procedures into the dental health workflow among National Dental Practice-Based Research Network (National Dental PBRN) affiliated practices.A target of 5 practitioners from the South-Central Region of the National Dental PBRN will be recruited to enroll between 5 and 8 patients each for a maximum of 40 patients. Patients will be enrolled during their dental appointment. Baseline patient demographic and characteristics and mental health screening data will be obtained. Patient follow-up data will be collected on screening experiences, which will be collected within approximately 1 week after each patient’s visit. Dental Office Personnel’s perceptions of feasibility will be obtained within approximately 2 weeks after all patient visits have been completed.     |
| **Objectives and Outcomes:** | Primary objective: To examine feasibility, acceptability, and appropriateness of integrating patient mental health screening and referral into the dental health workflow. Primary outcomes are based on RE-AIM implementation framework. RE-AIM is widely used for the planning and evaluation of practices in community and clinic settings.1, 2 For the current project, we focus on the following RE-AIM outcomes: ***Reach Outcomes*** Percentage of patients invited to enroll in the study who participate.***Effectiveness Outcomes***- Mean score on understanding of mental health topics and develop skills on how to address mental health topics with patients from pre-study to post-study.***Adoption Outcomes***-Percentage of dental practices to enroll in the study who participate-Percentage of consenting Dental Office Personnel trained in study procedures-Percentage of Dental Office Personnel who follow-up with patients who screen positive on their mental health screening form responses***Implementation Outcomes****-* Percentage of enrolled Dental Office Personnel who have a neutral/positive perception of the screening and referral to treatment procedures - Percentage of patient participants who have a neutral/positive perception of the screening and referral to treatment procedures- Percentage of Dental Office Personnel who report that the screening and referral to treatment procedures did not disrupt their workflow. |
| **Population:** | A target of 5 National Dental PBRN dental practices from the South-Central Region will enroll 5-8 patients each (for a maximum of 40 patients) to complete mental health and referral to treatment procedures.  |
| **Study Duration:** | Approximately 3 months  |
| **Subject Participation Duration:** | Approximately 1 week each patient and 3-months for dental office personnel  |
| **Estimated Time to Complete Enrollment:** | Practitioner Enrollment (to participate in study) = approximately 3 months Patient Enrollment = approximately 1 month |

**Schematic of Study Design**

|  |  |
| --- | --- |
| Dental OfficeEnrollment (Approx. 3 months) | Dental Office Personnel from a target of 5 dental offices from the South-Central Region who will participate in the study will undergo informed consent per regional IRB requirements (as participants). The regional PBRN study coordinator will document the screening via the Dental Office Screening Log. From each dental office, 1 to 2 dentists or dental hygienists involved in the study will undergo IRB/human subjects training, after which they will be trained in study procedures, including participant recruitment, study procedures, and data collection. As part of the study readiness process, the study PIs will work with the Dental Office Personnel to create a referral list specific to that dental office. The referral list will include mental health resources specific to the dental office’s surrounding community. Dental Office Personnel will complete the Provider Pre-study Survey.  |
|  |  |
| Patient screening and enrollmentat beginning of regularly scheduled dental visit(Approx. 30 minutes) | Between 5 and 8 patients per dental office (for a maximum of 40 total patients) will be identified from the dental practice’s list of patients for participation in the study during their next regularly scheduled dental office appointment. If the patient meets eligibility criteria, dental office personnel will explain the study and ask if he/she would be willing to participate. During this process, practitioners or designated office staff will complete the Consecutive Eligible Patient Enrollment Log. If the patient is interested in participating in the study, he/she will be offered a paper copy of the Informed Consent Form (ICF) if requested. The designated dental office personnel will answer any questions the patient may have and review the ICF. If the patient agrees to participate, he/she will be asked to complete an electronic ICF. |
|  |  |
| Patient Visit Survey Completion(Approx. 15 minutes) | The designated dental office personnel will ask subject if they have any further questions. Next, the patient will complete the Patient Demographic Form, the PHQ-2, GAD-2, CAGE-AID, and the Columbia-Suicide Severity Rating Scale. |
|  |  |
| Patient Visit Practitioner Response(Approx. 1 hour) | Upon completing the patient questionnaires, the patient will return the assessment to dental office staff. Dental practitioner will then check for completeness, respond as appropriate as designated in the study protocol, remind patient of follow-up survey, and thank the patient for their participation. |
|  |  |
| Follow-up(Patient = approx. 1 Week, approx.. 15 minutes to complete)(Dental Office Personnel = approx. 1 month) | Follow-up assessmentsPatient Post-Visit Survey will be sent to patient within 24 hours. Patient will complete the Patient Post-Visit Survey within approximately 1 week following completion of mental health screening. Dental Office Personnel completes the Provider Post-Visit Survey (within approximately 24 hours following each enrolled patient) and the Provider Post-Study Survey within approximately 2 weeks after all patient visits have been completed. |

# KEY ROLES AND CONTACT INFORMATION

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# 1 INTRODUCTION: BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

##  Background Information

In 2017, it was estimated that approximately 46.6 million adults, or approximately 19% of the adult population, had a mental health illness.3 Mental health diagnoses, comprising a spectrum of issues including depression, anxiety, substance abuse, etc., are a major issue in the United States.

Nearly one in five adults in the United States have struggled with mental illness in the last year, but over half of those individuals did not receive treatment during that time4 – which indicates the need for more referral networks for mental health.

A National Dental Practice-Based Research Network (PBRN) Quick Poll (n = 465) conducted in October 2018 found that nearly 93% of responding dentists reported a correlation between dental and mental health.5, 6 Unfortunately, this same poll found that only 51% of dentists ask any form of mental health questions, and of those, 73% indicated that the primary question they ask is whether the patient is under psychiatric care6 – which has little value for screening. Furthermore, no protocol exists for this service in dental offices.

The Mental Screening in Dental Practices (MSDP) study will be conducted in partnership with the National Dental PBRN (i.e., the Network). The Network is a consortium of U.S. dental practitioners, clinical researchers, and other stakeholders, working to improve oral health care through the conduct and dissemination of dental research and serving dental professionals through education and collegiality. The Network seeks to shorten the time from knowledge discovery to implementation in routine clinical practice by focusing its research on topics that are important to dentists’ everyday practice. The research, conducted by practitioners in dental offices, is designed to minimally impact the flow of routine clinical care and dental office operations. The Network has demonstrated the ability to recruit and engage practitioners in network studies and dissemination activities and change practice patterns of participating dentists.7-13 Data indicate that enrolled Network practitioners are similar to the general US dental provider population.5

## Rationale

Most mental health issues are identified and initially diagnosed in primary care settings. Yet problems plague this process: screening in primary care settings can be burdensome due to the number of screeners that are frequently required, resulting in the dilution or overlooking of those measures. Furthermore, the choice of screening measure is frequently determined by third-party payers (i.e., insurance companies) rather than providers. This loss of focus is costly to patients and to society – 44% of victims of suicide visited their primary care provider within one month of death.14 Though certainly not representative of all mental health conditions, these examples demonstrate the challenges associated with screening patients for mental health problems and appropriately referring them to suitable mental health care providers.

Unlike primary medical services, where screening for mental health concerns is standard practice, dental offices rarely perform mental health screenings as part of routine dental care despite regularly screening for a variety of important health related conditions.15-17 Additionally, individuals typically visit their dentist more frequently than their primary care medical provider.18, 19 In combination with most patients’ tendency to have a trusting relationship with their dentist,20 this makes dental offices an important source of goodwill for the healthcare community and an ideal environment to test the prospect of screening and referring patients to mental health services, as appropriate.

The MSDP study will use quantitative methods to collect the following data 1) patient perceptions of mental health screening and referral to treatment procedures, 2) dental office personnel perceptions of patients’ mental health screening and referral to treatment procedures, 3) number/characteristics of patients who complete screenings, 4) number/characteristics of dental offices who adopt procedures, 5) number of patients who are provided referral to mental health treatment.

The current study will apply the RE-AIM implementation framework.1, 2 The RE-AIM framework addresses the well-documented failures and delays in the translation of scientific evidence into practice and policy. RE-AIM is one of the commonly used planning and evaluation frameworks across the fields of public health, behavioral science, and implementation science. There have been over 700 publications that explicitly use RE-AIM for planning, evaluation (most often), or both. RE-AIM has been applied in a wide range of settings, populations, and health issues across diverse clinical and community contexts.

RE-AIM dimensions operate and are measured at both the individual level and multiple ecologic levels. Its key dimensions are reach and effectiveness (individual level), adoption and implementation (staff, setting, system, or policy/other levels), and maintenance (both individual and staff/setting/system/policy levels). Below is a description for each RE-AIM dimensions:

* Reach: The number and percentage of the target population willing to participate in the intervention out of the total eligible
* Effectiveness: Impact of an intervention on health outcome
* Adoption (system-level): The number and percentage of systems adopting procedure, and number/% of staff trained to implement procedure21, 22
* Implementation (system-level): Level of fidelity and costs to intervention elements and implementation strategies), percentage of implementation strategies delivered.
* Maintenance: Number of systems who continue the intervention/procedures following assigned protocol.

Due to the nature of the pilot study, the current project will focus on the RE-AIM dimensions of Reach, Effectiveness, Adoption, and Implementation. Due to the short-term and exploratory nature of the feasibility pilot study, we will not focus on the maintenance dimension of the RE-AIM framework.

**1.2.1 Potential Risks and Benefits**

Patients: There may be minimal privacy and psychological risks with completing mental health screening. There is minimal possibility of loss of privacy completing the screening form. Following completion of the screening forms, the dental office personnel may talk to the patient about his/her results in the exam room/private office space. During this time, other patients and/or dental personnel may overhear segments. Due to the exam rooms/private rooms being separated by walls, there is a remote chance that patients/dental office personnel may overhear conversations. As such, every possible precaution will be taken to ensure privacy of patient information within practice operatories – consistent with existing best practices in the dental practice of protecting patient information (i.e., ensuring that patient conversations occur in operatory room with no other patients/non-study personnel).

It is possible that some patients may feel psychological distress through the screening/referral to treatment process, as they will be sharing personal concerns and stressors that may exacerbate their mental health symptomology. If a patient experiences high distress, the dental office will respond in one of the following ways: 1) comforting the patient; 2) refer the patient to mental health services. The Regional Node Coordinator (RNC) will train Dental Office Personnel for managing such concerns before the beginning of study. When patients indicate tendency toward depression, anxiety, and/or substance abuse, the dental office will follow study protocols for providing referrals to mental health services in the operatory (see Section 4 – Study Schedule). When patients indicate positive suicide risk, Dental Office Personnel follow the study protocol (i.e., ensure patient is not alone, call 988 or 911, contact emergency contact in patient’s dental record, contact national suicide hotline). The RNC will train dental personnel for managing such concerns before the beginning of study.

As with any study, there is the possibility of breach of confidentiality. Appropriate precautions will be taken, and procedures will be followed to maintain confidentiality. These include use of unique study codes for participants, encryption of electronic data for transmission to the coordinating center, and password-protected computers for data storage. Compliance with all IRB regulations concerning data collection, data analysis, data storage, and data destruction will be strictly observed.

Dental Office Personnel: Participating Dental Office Personnel may become upset during completing forms regarding perceptions of mental health screening and referral to service procedures, this is expected to be transient. Additionally, dental office personnel may be become upset responding to patient’s mental health concerns Practitioners who experience distress may speak with the PIs and will be referred to counseling as necessary.

### Potential Benefits

Participation in the study will likely provide no direct benefit to participants*,* except possibly for those who receive an appropriate referral to a mental health professional for their condition identified from the screening.

The potential benefits of this study are that the results may contribute to the understanding of implementing mental health screening and referral to treatment procedures in dental offices.

Dissemination of research results beyond study participants may also benefit the broader dental care community. The study team will work with ARC and NCC staff, NIDCR, and external stakeholders to widely disseminate research results.

# OBJECTIVES AND OUTCOME MEASURES

## Primary

|  |  |  |  |
| --- | --- | --- | --- |
| **Objective** | **Description/Justification of Measure** | **Outcome Measured By**  | **When Completed** |
| To quantify the number of dental patients who agree to mental health screening during routine oral health care appointment | RE-AIM Dimension: ReachDental Office Personnel will complete the Consecutive Eligible Patient Enrollment Log, which will track the Number/% of patients who agree/do not agree to mental health screening | Percentages will be calculated, and then compare the percentage patients who agree to mental health screening to those who do not agree via the Consecutive Eligible Patient Enrollment Log  | At time of patient enrollment |
| To quantify the Dental Office Personnel’s attitude toward mental health from pre-study to post-study | RE-AIM Dimension: Effectiveness The practitioners will be asked to fill out a Pre-study survey and a Post-study survey. Both surveys contain the Mental Illness Clinicians’ Attitude Scale, which measures attitudes towards mental health/illness. | Calculating mean results, comparing scores of Provider Pre-study survey and Provider Post-study survey. | At beginning of study prior to patient enrollment (Provider Pre-study Survey) and within two weeks after study (Provider Post-study Survey). |
| To quantify the extent to which dental offices and personnel adopt a particular practice via the following:a) Percentage of dental practices to enroll in the study who participateb) Percentage of consenting Dental Office Personnel trained in study proceduresc) Percentage of Dental Office Personnel who follow-up with patients who screen positive on their mental health screening form responses | RE-AIM Dimension: Adoption1. NC will complete the Dental Office Screening Log, which will track the Number/% of dental clinics that adopt/do not adopt mental health screening and referral to treatment procedures
2. NC will complete the Dental Office Screening Log, which will track the Number/% of dental office personnel trained in study procedures
3. Dental Office Personnel will complete the Provider Post-Visit Survey, which will track Number/% of dental office personnel who will follow-up with patients during the same visit who screen positive about mental health screening forms
 | 1. Calculating the percentage and comparing the dental clinics that adopt health screening and referral to treatment procedures to those that do not adopt mental to treatment procedures via Dental Office Screening Log
2. Calculating the percentage and comparing the percentage dental office personnel who agree to be trained in study procedures to dental office personnel that do not agree to be trained in study procedures
3. Calculating the percentage and comparing the percentage dental office personnel who will follow-up with patients who screen positive on mental health screening forms to Number/% of dental office personnel who do not follow-up with patients who screen positive on mental health screening forms Post-Visit Survey
 | 1. During dental practice enrollment
2. Between practitioner consent and patient enrollment
3. Within 24 hours after patient visit
 |
| To evaluate workflow feasibility and acceptability. Implementation metrics for this study include:a) Percentage of enrolled Dental Office Personnel who have a neutral/positive perception of the screening and referral to treatment procedures b) Time spent in the screening and referral to treatment procedures1. Percentage of patient participants who have a neutral/positive perception of the screening and referral to treatment procedures
2. Percentage of Dental Office Personnel who report that the screening and referral to treatment procedures did not disrupt their workflow.
 | RE-AIM Dimension: Implementation: 1. Dental Office Personnel will be asked to complete the Provider Post-Visit Survey, which includes Feasibility and Acceptability Questionnaire, which measures perceptions regarding screening and referral to treatment procedures
2. Dental Office personnel will be asked to complete the Provider Post-Visit Survey, which will ask about time spent in the screening and referral to treatment procedures
3. Patient will receive the Patient Post-Visit Survey within 24 hours of their visit, which includes the Appropriate Questionnaire (and other questions), which asks perceptions of screening and referral to treatment process
4. Dental Office personnel will be asked to complete the Provider Post-Visit Survey, which will ask about workflow disruption due to mental health screening and referral to treatment procedures
 | 1. Calculate mean score for questions on perceptions of screening and referral to treatment procedures via the Provider Post-study Survey
2. Calculate time spent time spent in the screening and referral to treatment procedures via Provider Post-visit Survey
3. Calculate mean score for questions on perceptions of screening and referral to treatment procedures via the Patient Post-Visit Survey
4. Calculate mean score for questions on workflow disruption due to mental health screening and referral to treatment procedures via Provider Post-visit Survey
 | 1. Within two weeks of study completion
2. Within 24 hours of patient visit
3. Within one week after all patient visits

d) Within 24 hours of patient visit |
|  |  |  |  |

# STUDY DESIGN

* This is a prospective pilot study regarding the feasibility of mental health screening and referral to treatment procedures in dental care workflows. These procedures will screen for selected mental health concerns among patients as a part of their dental visit among practices of Dental Office Personnel who are a part of the National Dental PBRN. The study will allow an opportunity to inform our knowledge of implementing mental health screening and referral to treatment procedures within the standard dental care workflow. The study will describe the implementation of procedures provided to dental practices and perceptions of dental office personnel and patients.
* Between 5 and 8 patients per office will be recruited from 5 private practices within the South-Central Node of the National Dental PBRN will participate in the study (for a maximum of 40 patients). Other participants include Dental PBRN practitioners (i.e., Dental Office Personnel) and office staff from those practices who will be involved in the process of feasibility testing. We anticipate a total of approximately 5 dentists, 10 dental hygienists, 10 dental assistants and 10 office staff will participate.
* The South-Central Node Coordinator/Investigators will recruit Dental Office Personnel to enroll in the pilot study.
* One to two selected Dental Office Personnel who will participate in the recruitment, consenting and data collection for their respective practice will complete human subjects (IRB) training and/or submit verification of this training. Study procedure training will be provided in advance of recruitment by the South Central Node Coordinator and/or the research team. These individuals will recruit and enroll patients into the study during routine visits.
* The patient population will comprise patients who receive dental care or dental examination from practitioners of the South-Central Node of the National Dental PBRN. Prospective participants will be identified by practitioners or office staff and invited to enroll in the feasibility pilot study. Potential participants include patients who are on the schedule for the next two-three weeks.
* Upon arrival at their regularly scheduled appointment, patients will be contacted by the designated dental office personnel to seek their interest in the study. In this study, designated dental office personnel will review the Informed Consent Form, answer any questions the potential participant may have, ask the patient to complete the electronic consent and provide them with a copy of the Informed Consent Form. The occurrence of eligible patients who decline participation in the study will be noted in the Consecutive Eligible Patient Enrollment Log.
* Upon completing the Patient Demographic Form, the PHQ-2, GAD-2, CAGE-AID, and the Columbia-Suicide Severity Rating Scale electronically, the patient will return the study provided tablet to dental office staff. Dental practitioner will then check for completeness, respond as appropriate as designated in the study protocol (Section 4.3), remind patient of follow-up survey, and thank the patient for their participation.
* Practitioners and patients will provide data electronically via tablets. Patient-reported data will be collected via personal tablets, smart-phones, or computers after in-office visits (i.e., Patient Post-visit Survey). Practitioner-reported data will be collected via tablets, smart-phones, or computers after in-office visits (i.e., Practitioner Post-Visit Survey; Practitioner Post-Study Survey).
* Patient will receive Patient Post-Visit Survey within 24 hours of their visit and be instructed to complete the Patient Post-Visit Survey within approximately 1 week following the dental visit.
* Dental Office Personnel completes the Provider Post-Visit Survey (within approximately 24 hours following each enrolled patient)
* Dental Office Personnel completes Provider Post-Study Survey approximately 2 weeks after all patient visits have been completed.
* We anticipate the enrollment of dental offices (and Dental Office Personnel) will take 1 month, and patients will take 1 month.
* Node coordinator(s) will track number and percentage of clinics invited/participating and reasons for not participating via the Dental Office Screening Log.
* Dental Office Personnel will track number and percent of eligible patients who participate/do not participate in mental health screening via the Consecutive Eligible Patient Enrollment Log.
* All data will be transmitted directly to the centralized study database provided by the NCC.
* Practitioner and practice characteristics from the National Dental PBRN Enrollment Questionnaire will be combined with data collected for this pilot study

## Practitioner Inclusion Criteria

**Dental Hygienist/Dental Assistants/Dental Office Staff/Dentist:** To be eligible to participate in this study, practitioners must meet the following criteria:

* Age ≥ 18 years
* Be or become an active member of the National Dental PBRN ( <http://nationaldentalpbrn.org/enrollment.php>).
* Willing to consent patients to the study following regionally approved procedures
* Be appropriately licensed in the U.S. to provide dental care for adult patients in the South-Central region, licensed in the US to treat patients, and actively providing dental care for adult patients
* Able to receive emails
* Willing to comply with all study procedures and be available for the duration of the pilot session
* Does not anticipate retiring, selling the practice, moving during the study
* Able to complete Human Subjects and Study Protocol Training

**Additional Dentist Criteria:** In addition to the above, dentists must also meet the following criteria in order to be eligible to participate in this study:

* Have WIFI in the practice
* Affirm that the practice can devote sufficient time in patient scheduling to allow focused recording of all data required for the study

## Patient Inclusion Criteria

For patient participants to be eligible to participate in this study, a patient must meet all the following criteria:

* Must be able to access working email
* English-speaking
* Must have access to the Internet
* Provide dated, informed consent
* 18 years of age or older at the time of study enrollment
* Receives dental care at a National Dental PBRN South-Central Regional Node participating dental office

## Patient Exclusion Criteria

* Previously enrolled in the study

## Strategies for Recruitment and Retention

### Practitioner Recruitment and Retention

The network practitioner database will be used to identify practitioners to recruit for this study. The South-Central National Dental PBRN Node Coordinator (NC) will determine possible interest of dental offices by contacting dental practices enrolled in the National Dental PBRN (South-Central Region). The NC will provide information about the purpose of the study. The South-Central NC will send a recruitment email with the study information sheet (Appendices B and C, respectively).

We will begin patient enrollment once a dental practice is enrolled in the study. We will strive to complete patient enrollment (for a maximum of 40 patients) within one month following enrollment of the five dental practices. Consequently, it is anticipated that approximately 5 dental offices will be needed to complete patient enrollment during the practitioner-specific enrollment period. Each practitioner may contribute between 5 and 8 patient enrollments for the study.

The South-Central NC will recruit practitioners in the South-Central Node. Retention will be an important aspect of the cohort study, and the design of all aspects of the study will take into consideration the burden to the practitioner and the retention of participants. The study team and NCs will maintain efforts to engage practitioners throughout the duration of the study, including addressing practitioner questions and concerns and implementing processes to streamline data collection in dental offices.

Dentists will receive $100.00 incentive for participating in and completing the study per patient involved. Dental Hygienists will receive $75.00 incentive for participating in and completing the study per patient involved. Dental assistants and office staff members will receive $50.00 for participating in and completing the study per patient involved. Another incentive of joining this study is the dental practice will receive a mental health referral list customized to their practice.

All practitioners will receive an additional $40.00 for completing both the pre- and post- study surveys. Each clinic will also be allowed to keep a study-purchased tablet computer (approximately $300 each) that will be used for data collection in the clinic.

Additionally, designated personnel from each dental practice will receive training in human subjects research, if needed, for the sake of recruiting patients to the study and interacting with them regarding their responses to the questionnaire. The individuals in this role should at minimum include a dentist and dental hygienist.

Dentists/Dental Hygienist/Dental Office Assistants/Dental Office Staff will be remunerated once they have completed the following: consent, Dental PBRN Enrollment Questionnaire (EQ) form (or updates to the EQ if more than 1-year-old), participation in the screening and referral to service process, Consecutive Eligible Patient Enrollment Log, Provider Pre-Study Survey, Provider Post-Visit Survey(s), and Provider Post-Study Survey at the end of the study.

### Patient Recruitment and Retention

The target sample size for this observational study is a maximum of 40 patients. Patients will be recruited by Dental Office Personnel over a recruitment period of approximately one month. Practitioners will be asked to use a consecutive enrollment strategy. Each practitioner will establish a regular recruitment period (days and/or times) each week that fits the practice and is sufficient to meet enrollment targets. Potential participants include patients who are on the schedule for next 2-3 weeks. A Consecutive Eligible Patient Enrollment Log will be used to record potential patient refusal/non-enrollment among patients who are eligible for the study and, where possible, reasons for non-enrollment, during established recruiting periods.

Upon arrival at their regularly scheduled appointment, patients will be contacted by the designated dental office personnel seek their interest in the study. In this study, designated dental office personnel will review the Informed Consent Form, answer any questions the potential participant may have, ask the patient to complete the electronic consent and provide them with a copy of the Informed Consent Form. The occurrence of eligible patients who decline participation in the study will be noted in the Consecutive Eligible Patient Enrollment Log.

Following confirmation of receipt of consent and time for the dentist office personnel to answer any questions the patient may have; the patient will be provided with the mental health screening materials. Participants may withdraw at any time.

Patients will receive a check for $40.00 for participating in and completing the study. Completion of the study involves the following: consent, participation in screening and referral to service process, and completion of the Patient Post-Visit Survey. Payments will be processed for completing all parts of the study. Patients must complete the in-office forms and the Patient Post-Visit Survey within one week of receiving it to receive payment.

We anticipate this will result in the following numbers of practices and participants:

|  |  |  |  |
| --- | --- | --- | --- |
| **Line** | **Entity** | **Per Practice** | **Approximate Total**  |
| 1 | Practices | - | *5* |
| 2 | Dentists | 1 | 5 |
| 3 | Dental Hygienist | 1 to 4 | 1 to 20 |
| 4 | Office Staff/Dental Assistants | 1 to 8 | 1 to 40 |
| 5 | Dental Patients | 5 to 8 | 40 |
|  | **Total (lines 2-5)** | **8 to 21** | **32 to** **90** |

## Participant Withdrawal

### Reasons for Participant Withdrawal

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

### Handling of Participant Withdrawals

In the case of participant withdrawal from the study, staff will only attempt continued follow-up data collection for participants who are withdrawn due to an unanticipated problem/serious adverse event (see Assessment of Safety, Section 6 below). In those cases, only data related to the completion of reporting requirements for the unanticipated problem will be recorded. Participants withdrawn from the study for any other reason will have the date and reason for withdrawal recorded but will not have any additional study data recorded. Although participants withdrawn from the study may continue to receive routine clinical care as patients of the participating dentists, additional study data will not be collected from this continuing clinical care (except as noted above).

Replacement of participants who withdraw or discontinue early will be allowed, but only during the enrollment period for each Dental Office Personnel. Each may attempt to enroll one replacement participant for each participant enrolled who withdraws or discontinues during the practitioner-specific enrollment period.

## Premature Termination or Suspension of Study

This study may be suspended or prematurely terminated if there is sufficient reasonable cause. The Principal Investigator is responsible for promptly notifying all parties and providing the reason(s) for the termination or suspension.

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

Insufficient adherence to protocol requirements.

Data that are not sufficiently complete and/or evaluable.

Determination of futility.

# STUDY SCHEDULE

Practitioners enrolled in the National Dental PBRN across the South-Central region who express interest in the study and meet eligibility criteria will be invited to participate. Study information and instructions will be provided to interested practitioners by RNC. After practitioners are eligible and enrolled, RNC/Study Team will describe the participant selection procedures, methods for approaching patients and obtaining informed consent, methods for data collection, and other study procedures for the Dental Office Personnel who will help to execute the study. A summary flow chart will provide an overview of all study visits and study procedures/data collection for each visit. The NCC will conduct training with the South-Central NC, who will train staff and dentists in each practice. In addition, the NC will conduct in-person or remote protocol and electronic data management system training with practitioners and office staff prior to initiating the study. The training ensures that the practitioner and staff understand the study procedures and receive instruction on the consent process and the electronic data capture system. The NCs/Investigators will maintain close contact with the practitioners prior to and throughout the study implementation period*.*

The study schedule will proceed in the following stages Dental Office Personnel:

1. The South-Central Region will enroll practitioners into the study to obtain a total of approximately 5 dental practices
2. Practitioners from these offices will complete activities to be deemed research-ready and study-ready
3. NCs will train research-ready and study-ready practitioners and their office staff in the appropriate study procedures
4. Following Dental Office study agreement, the Node Coordinator and Study Investigators will work with each site as needed to identify local mental health resources to whom a patient may be referred (i.e., county mental health departments)
5. Node Coordinator and Study Investigators will ensure that all enrolled dental office personnel will be aware of the Suicide Prevention Hotline
6. Practices will screen and enroll eligible patients into the study

The Study Team, NCC and Node personnel will coordinate the launch of the study. Participating practitioners will be enrolled over a period of approximately 1-month. Practitioners will begin study recruitment as soon as possible following study training with an NC.

## Dental Office Personnel Enrollment Schedule

1. Verify practitioner inclusion/exclusion criteria
2. Practitioner and eligible consent procedures
3. Practitioner and eligible staff participate in study training with an NC/Investigators

Following Dental Office Personnel Consent:

* Dental Office Personnel Pre-Study Survey (approximately 10 minutes) consisting of perceptions regarding:
	+ The process of mental health screenings,
	+ The process of referral to mental health treatment options,
	+ Implementation barriers and facilitators for integrating mental health screening and referral to treatment procedures into your dental health workflows, and
	+ Relevance/interest on this topic.

Following each patient visit, Dental Office Personnel will complete the following online:

* Provider Post-Visit Survey (approximately 5 minutes) consisting of basic details of the patient interaction including whether or not a referral was provided, time spent in the interaction, etc.

Following study completion, Dental Office Personnel will complete:

* Provider Post-Study Survey (approximately 10 minutes) consisting of perceptions regarding:
	+ The process of mental health screenings,
	+ The process of referral to mental health treatment options,
	+ Implementation barriers and facilitators for integrating mental health screening and referral to treatment procedures into your dental health workflows, and
	+ Relevance/interest on this topic.

### Referral List

As part of the study readiness process, the study PIs will work with the Dental Office Personnel to create a referral list specific to that dental office. The referral list will include mental health resources specific to the dental office’s surrounding community. If a patient screens positive for a mental health issue, REDCap will flag the patient’s record, and instruct the Dental Office Personnel to either provide a physical copy of the referral list to the patient or call a resource on the list on behalf of the patient.

## Patient Screening/Enrollment Schedule

Patients will be recruited and enrolled during their regularly scheduled appointment.

### Patient Screening and Enrollment

Upon arrival at their regularly scheduled appointment, patients will be contacted by the designated dental office personnel to seek their interest in the study. In this study, designated dental office personnel will review the Informed Consent Form, answer any questions the potential participant may have, ask the patient to complete the electronic consent and provide them with a copy of the Informed Consent Form. Participants may withdraw at any time. The occurrence of eligible patients who decline participation in the study will be noted in the Consecutive Eligible Patient Enrollment Log.

Following and time for the dentist office personnel to answer any questions the patient may have; the patient will be provided with the mental health screening materials.

## Patient Visit

After the patient has consented, they will complete the following via tablet:

* The *Patient Demographic Form* – This form asks for basic contact information about the patient including name, address, phone number, and a backup contact. It also asks about demographic characteristics including gender, birthdate, race, form of dental/health insurance, education level, and annual household income level.
* *Patient Health Questionnaire-2* (PHQ-2) – The PHQ-2 is a validated two question screening tool for depression commonly used in primary care settings.23 The two questions ask if, over the last two weeks, the respondent has felt less interest in doing things and felt down, depressed, or hopeless respectively. Answers for each are scored from 0-3 indicating ‘Not at all’ to ‘Nearly every day’ respectively. If the aggregate score is 0, no action is needed. If the aggregate score is 1-2, a referral list will be provided to the patient. If the aggregate score is higher than 2, a referral list will be provided to the patient and the dental practitioner will offer to call the referral as well.
* *Generalized Anxiety Questionairre-2 (GAD-2)* – The GAD-2 is a validated and commonly used measure of general anxiety.24 The two questions ask about the frequency with which the respondent feels nervous or on edge and how frequently they struggle to control their worrying. It uses the same response options and is scored on the same scale as the PHQ-2. Recommendations to dental practitioners based on this scale are the same as with the PHQ-2 (score=0, no action needed; score = 1-2, provide referral list; score = above 2, provide referral list and offer to call the referral).
* *CAGE-AID* – The CAGE-AID is a frequently used and validated measure used in primary care to discern the extent to which substance use behavior, including alcohol use, interferes with the respondents’ ability to function without those substances and the extent to which it interferes in their relationships.25, 26 It is composed of four Yes/No questions where a “Yes” is scored as 1 and a “No” is scored as 0. If a respondent’s aggregate score is 0 (meaning the answer to all four questions is “No”), no action is needed. If the aggregate score is 1 or more, the recommendation to the dental professional will be to provide a referral list to the patient and offer to call that referral on behalf of that patient as well.
* *Columbia-Suicide Severity Rating Scale (C-SSRS)* – The C-SSRS is a validated scale designed to gauge an individual’s suicidal ideations and whether that individual has a plan to end their life.27 It is composed of 6 interdependent questions to which the participant responds. Scoring is as follows:
* Negative responses to both Question 1 and Question 2 result in the respondent continuing to the next CRF/set of questions.
* An affirmative response to Question 1 results in a recommendation to provide a referral list for to mental health services to the patient.
* An affirmative response to Question 2 directs the patient to the remaining questions.
* A negative response to Question 2 directs the patient to Question 6.
* An affirmative response to Question 3 results in a recommendation to provide a referral list to mental health services to the patient.
* An affirmative response to either Question 4 or Question 5 results in a recommendation to the dental practitioner to call 911 and/or 988 on behalf of the patient.
* An affirmative response to Question 6 (Lifetime) results in a recommendation to provide a referral list to mental health services to the patient.
* An affirmative response to Question 6 (Past 3 months) results in a recommendation to the dental practitioner to call 911/988/on behalf of the patient.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| PHQ-2 | GAD-2 | CAGE-AID | C-SSRS | Action Steps  |
| Score  | Score  | Score  | Affirmative Response |
| 0 | 0 | 0 |  | None  |
| 1-2 | 1-2 |  |  | Provide referral list to patient  |
| >2 | >2 | >=1 | Q1, Q3 only, Q6 (lifetime) | Dentist notified |
| Provide referral list to patient/Ask patient to call referral  |
|  |  |  | Question #4 or #5, Question #6 (Past 3-Months) | Dentist notified  |
|  |  |  | Dental office will ensure patient is not alone. |
|  |  |  | Dentist office calls one of the following: |
|  |  |  | * 988
 |
|  |  |  | * 911
 |
|  |  |  | * Emergency contact in dental record
 |

* Immediately after a patient completes the forms (via tablet), the designated dental office personnel will review the completed forms (see immediately above).
	+ Verify completeness of forms. If there are missing items, the dental office personnel will return the tablet to the patient to request additional information. All questions on the validated instruments are required. Patients who decline to answer questions on the validated instruments will be withdrawn from the study.
	+ All screening scores will be supplied to dental office personnel. In all cases except in cases of active risk of suicide, any positive screening will result in providing a referral list and/or offering to call the referral.

## 4.4 Following Patient Visit

Following the patient visit, the patient will receive an email link to complete electronically:

* Patient Post-Visit Survey (within 1-week)

## 4.5 Withdrawal Visit

If a patient withdraws from the study, the following is completed via the Consecutive Eligible Patient Enrollment Log:

* Record date and reason for withdrawal.
* Record information needed to address a safety event that may have led to the patient’s withdrawal from the study
* Record other participant information only if consent was not withdrawn. Additional information recorded should only be that which is required for the visit type, as applicable (see above).

# STUDY PROCEDURES/EVALUATIONS

The intent of this pilot study is to evaluate the patient and dental office perceptions of feasibility on integrating mental health screening and referral to treatment procedures into the dental health workflow using a pilot study involving Dental PBRN affiliated practices.

## Study Procedures/Evaluations and Questionnaire Administration

* All baseline and follow-up data will be collected electronically.

**5.1.1 During Recruitment of Dental Practice Staff:**

* NC/Study Team will complete the Dental Office Screening Log

**5.1.2 Following Consent of Dental Office Personnel (e.g., all dental office personnel who participate in the study):**

* Dental Office Personnel Pre-Study Survey

## 5.1.3 During Patient Recruitment

* Dental Office Personnel will complete the Consecutive Eligible Patient Enrollment Log
* Patient will be invited to participate upon arrival for their appointment
* Patient will be provided a copy of the Informed Consent Form
* Dental Office Personnel will be available to discuss the study, answer any questions, review the consent, and ask the patient to complete the electronic consent.

**5.1.4 Following Patient Consent**

* Patients will complete *Patient Demographic Form, Patient Health Questionnaire-2, Generalized Anxiety Questionnaire-2, Columbia-Suicide Severity Rating Scale, and CAGE-AID*

## 5.1.5 Following Patient Visit

* Following the patient visit (within 1 week), the patient will complete online:
	+ Patient Post-Visit Survey
* Within 24 hours following the patient visit, Dental Office Personnelwill complete:
	+ Provider Post-Visit Survey

## 5.1.6 Following Completion of Study

* Approximately two weeks after the last enrolled patient, Dental Office Personnel will complete:
	+ Provider Post-Study Survey

## Development of data collection instruments

Survey development has included refinement of data collection instruments with an emphasis on reducing overall burden and improving acceptability. Surveys have been derived from validated instruments, when possible.

Dental Office Personnel and patient questionnaires to be utilized in this study have undergone an informal cognitive interviewing process with the National Dental PBRN Practitioner Executive Committee (PEC) members. All questionnaires have been reviewed by the NCC (including a biostatistician) and the ARC regarding appropriateness of instruments/questions chosen and data collection processes. PEC members also provided feedback on their understanding of the survey content in general, appropriateness of content for the setting, and length of time necessary for completion for Dental Office Personnel and patient surveys.

# ASSESSMENT OF SAFETY

## Definitions of Safety Parameters

### Serious Adverse Event

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

* Results in death
* Is life-threatening (places the participant at immediate risk of death from the event as it occurred)
* Results in inpatient hospitalization or prolongation of existing hospitalization
* Results in a persistent or significant disability or incapacity
* Results in a congenital anomaly or birth defect
* Based upon appropriate medical judgment, the event may jeopardize the participant’s health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

### Unanticipated Problems

The Office for Human Research Protections (OHRP) considers unanticipated problems involving risks to participants 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 participant 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 participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

## Specification of Safety Parameters

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

## Reporting Procedures

### Unanticipated Problem Reporting

Per National Dental PBRN procedures, unanticipated incidents and events will be reported to the PI(s). After the PI(s) is made aware of the incident/event, the following procedures will be followed.

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

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

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

* Unanticipated problems that are serious adverse events will be reported to the IRB as soon as possible or within 5 working days of the investigator becoming aware of the event.
* Any other unanticipated problem will be reported to the IRB within 10 working days of the investigator becoming aware of the problem.
* All unanticipated problems should be reported to appropriate institutional officials (as required by an institution’s written reporting procedures), the supporting agency head (or designee), and OHRP within one month of the IRB’s receipt of the report of the problem from the investigator.

All unanticipated problems will be reported to NIDCR concurrently with reporting to the IRB. These reports will be made to NIDCR’s centralized reporting system via the Clinical Research Operations and Management Support (CROMS) contractor.

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

# STUDY OVERSIGHT

The three PIs, Drs. Berryhill, Culmer, and Smith, will be responsible for study oversight, including monitoring safety, ensuring that the study is conducted according to the protocol and ensuring data integrity. The NCC will provide the PIs with current data summaries, and the PIs will review the data for safety concerns and data trends at regular intervals and will promptly submit reportable events to the IRB and NIDCR that arise during the conduct of the study, per the IRB’s reporting time-frame requirements. To ensure data integrity, the PIs, NCC, and study team will adhere to data quality management processes (please see Section 11).

In addition to the PIs’ responsibility for oversight, study oversight will be
under the direction of the NIDCR Medical Monitor. The PIs will submit reports to
NIDCR Medical Monitor for review at six months after study initiation until enrollment
targets have been met, and then six-monthly thereafter until the study has ended. Medical Monitor reports will include data regarding enrollment and retention, unanticipated problems and protocol deviations, primary outcome measures, quality management findings and other relevant parameters. If necessary, additional steps may be taken to ensure data integrity and protocol compliance.

# CLINICAL SITE MONITORING

## Site Monitoring

For Network studies, Quality Management procedures and clinical site monitoring (if needed) are conducted to ensure that the study is implemented in accordance with the protocol and other operating procedures, the quality and integrity of study data and data collection methods are maintained, and the safety of human subjects is ensured. For this study, clinical site monitoring is not required, but NIDCR reserves the right to request in-person site monitoring if warranted.

## Site Monitoring Determination

Site monitoring may be needed if there are issues at a practitioner location or office that cannot be addressed via Network quality management processes and office staff re-training. Examples include determining the root cause of an unresolved issue, problematic data found via other quality management processes (e.g., study monitoring reports), and/or problems with informed consent. Efforts will be made to work with the practitioner to resolve site issues before considering a remote or in-person site monitoring visit. In addition, for-cause visits at practices or Central or Node Administrative Sites can be mandated by the NIDCR Office of Clinical Trials Operations & Management (OCTOM), its designees, or can be requested by the NCC, regional staff, or practices.

## Scope of Monitoring Activities

Should there be a need, for-cause study monitoring will be detailed in a Clinical Monitoring Plan developed by NIDCR’s CROMS contractor in conjunction with NIDCR. NIDCR will determine where a monitoring visit may occur (e.g., practice, regional Node, central administrative site), whether a for-cause monitoring visit will be performed through the CROMS contractor, and the extent to which network personnel may provide support towards obtaining the documentation needed for the monitoring visit. OCTOM will also determine whether a monitoring visit will be conducted in-person or remotely. The intent of the visit is to address any problems or issues encountered that may require additional training, remediation, or in-person assistance. The scope of the visit will be determined by the issue(s) identified.

# STATISTICAL CONSIDERATIONS

## Study Hypotheses

|  |
| --- |
| ***Reach*** H1: 80% of patients invited to enroll in the study will participate  |
| ***Effectiveness***H2: Practitioners will report an improved attitude toward mental health from pre-study to post-study |
| ***Adoption*** H3: 80% or more of dental practices approached to enroll in the study agree to participate |
| H4: 100% of consenting Dental Office Personneltrained in study procedures  |
| H5: 80% of Dental Office Personnelwill follow-up with patients about mental health screening form responses  |
| ***Implementation***H6*:* 80% or more of enrolled Dental Office Personnel will have a neutral/positive perception of the screening and referral to treatment procedures  |
| H7: 80% of patient participants will have a neutral/positive perception of the screening and referral to treatment procedures  |
| H8: 80% of Dental Office Personnel will report that the screening and referral to treatment procedures did not disrupt their workflow  |

## Sample Size Considerations

This is a pilot study to test assess the feasibility of testing mental health screening and referral to treatment procedures in dental practices. We determined that recruiting 5 practices and a maximum of 40 patients (a maximum of 8 per practice) would suffice for assessing feasibility extent to which an intervention can be successfully used or carried out within a setting, acceptability (perception among implementation stakeholders that a given intervention is agreeable), and appropriateness28 (perceived fit/compatibility of the intervention in a given practice setting), of integrating mental health screening and referral procedures into dental practice workflows (among providers and patients).

## Final Analysis Plan

Since this is a feasibility study, analyses will be descriptive in nature. The table below outlines the analysis plan for each hypothesis.

|  |  |  |
| --- | --- | --- |
| **Hypothesis**  | **Measure**  | **Analysis Plan**  |
| ***Reach*** H1: 80% of patients invited to enroll in the study will participate  | Consecutive Eligible Patient Enrollment Log  | Calculate the number/% of patients who consent versus patients who do not consent  |
| ***Effectiveness***H2: Dental Office Personnel will report an improved attitude toward mental health from pre-study to post-study. | Mental Illness Clinicians’ Attitudes Scale per the Provider Post-Visit Survey  | Compare means from pre-study to post-study via paired sample t-testImproved attitude = higher mean score on post-study of Mental Illness Clinicians’ Attitudes Scale compared to pre-study |
| ***Adoption*** H3: 80% or more of dental practices approached to enroll in the study agree to participate | Dental Office Screening Log  | Calculate the number/% of dental clinics that adopt mental health screening and referral to treatment procedures  |
| H4: 100% of consenting Dental Office Personnel trained in study procedures | Dental Office Screening Log  | Calculate the number/% of dental clinics that are trained in study procedures  |
| H5: 80% of Dental Office Personnel will follow-up with patients who screen positive on mental health screening forms  | Provider Post-visit Survey | Calculate the number/% of Dental Office Personnel who follow-up who screen positive on mental health screening forms |
| ***Implementation***H6*:* 80% or more of enrolled Dental Office Personnel will have a neutral/positive perception of the screening and referral to treatment procedures  | Feasibility, Appropriateness, and Acceptability Questionnaire per the Provider Post-Study Survey  | Calculate mean scores of items Neutral/positive perception = Mean score of 3.0 or greater |
| H7: 80% of patient participants will have a neutral/positive perception of the screening and referral to treatment procedures | Feasibility, Appropriateness, and Acceptability Questionnaire per the Patient Post-Study Survey | Calculate the mean score items Neutral/positive perception = Mean score of 3.0 or greater |
| H8: 80% of Dental Office Personnel will report that the screening and referral to treatment procedures did not disrupt their workflow. | Item per the Patient Post-Visit Survey  | Calculate the mean score of relevant item No disruption = Mean score of 3.0 or greater  |

# SOURCE DOCUMENTS AND ACCESS TO SOURCE DATA/DOCUMENTS

Each participating practice and the NCC will maintain appropriate research records for this study, using the principles of and complying with regulatory and institutional requirements for the protection of confidentiality of subjects. Each practice and the NCC will permit authorized representatives of NIDCR and regulatory agencies to examine (and when required by applicable law, to copy) research records for the purposes of quality assurance reviews, audits, and evaluation of the study safety, progress and data validity.

The following will be considered source documents for this study and will be maintained by the NCC via an EDC:

* Dental Office Screening Log (completed by NC)
* Dental PBRN EQ Form (completed by Dental Office Personnel; includes additional questions)
* Provider Pre-Study Survey
* Consecutive Eligible Patient Enrollment Log (completed by Dental Office Personnel after training)
* Patient Demographic Form (completed by patient)
* CAGE-AID (completed by patient)
* CSSRS (completed by patient)
* GAD-2 (completed by patient)
* PHQ-2 (completed by patient)
* Patient Post-Visit Survey (completed by patient)
* Provider Post-Visit Survey (completed by all Dental Office Personnel who interacted with the patient)
* Provider Post-Study Survey (completed by all Dental Office Personnel who interacted with any patient during the study)

All study source documents must be maintained in a secure manner, and authorized practice, ARC, or NCC personnel will have access to the source documents stated above.

# QUALITY CONTROL AND QUALITY ASSURANCE

For quality management activities associated with data collection and processing, standard procedures for National Dental PBRN studies include automatic data quality checks in the EDC for each electronic CRF and the processes related to the manual review of data, discrepancy management, delinquent data handling, data updates, data verification and approval, and database audit. The EDC will be programmed with edit checks and response limiters to reduce data response errors. If out of range values are entered by the patient or provider, the individual will be alerted and asked to provide a value that is in range.

Reports will be created from the EDC system for the study team to address data accuracy and completeness. NCs will work directly with practices to address data discrepancies and/or missing data/CRFs. The PI will work closely with the NCC to ensure that the electronic CRFs are collected appropriately, and that confidentiality is being maintained according to protocol-specified procedures. Conference calls will be held approximately every month during the data collection phase with the study team and ARC and NCC personnel including NCs to monitor progress, manage study documentation and procedures, and troubleshoot any problems.

# ETHICS/PROTECTION OF HUMAN SUBJECTS

## Ethical Standard

The PI, study team, and ARC and NCC personnel 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.

## Institutional Review Board

The protocol and written information sheet will be submitted to the Central IRB for review and approval. Recruitment materials and all participant materials will undergo local context review by ceding IRBs. Approval of both the protocol and the consent form(s) must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the Central IRB before the changes are implemented in the study.

## Informed Consent Process

**Practitioners:** The designated RNC will execute consent procedures for the study practitioners/dental hygienist/dental office staff. The Dental Office Personnel must complete required IRB training and study specific training. Consent procedures on patients will be administered prior to performing any study-related assessments or procedures.

**Patients**: Participating practices will designate who will execute consent procedures for the study. In most cases this will be the participating dentist or his/her designee (e.g., dental hygienist/dental office staff). Any personnel who will be assigned to obtain consent will be defined as study personnel and must complete required IRB training. Consent procedures will be administered prior to performing any study-related assessments or procedures.

The patient’s consenting process will be initiated via a conversation with the practitioner pursuant to the overseeing IRB requirements. The Dental Office Personnel will explain the research study to the patient, answer any questions that may arise, and discuss risks and possible benefits of study participation, if applicable. The practitioner will hand the patient a tablet with the digital consent form pulled up, the patient will be enrolled in the study once they electronically review and sign the consent and click submit. If required by the responsible IRB, an electronic or paper consent form describing in detail the study procedures and risks will be given to the patient or practitioner to read and review the document or have the document read to him or her. If the patient is interested in participating in the study, he/she will be offered a paper copy of the Informed Consent Form (ICF) if requested. The participant will complete the consent document, and a copy of the consent document will be emailed or given to the patient or Dental Office Personnel for his/her records if applicable. The consent process will be documented in the research record. Patients or Dental Office Personnel may withdraw consent at any time throughout the course of the study.

## Exclusion of Women, Minorities, and Specific Age Groups

## For the study, there are no exclusions based on gender, race or ethnicity. Study participation will be limited to adults aged 18 and over.

## Participant Confidentiality

Participant confidentiality is strictly held in trust by the investigators, study staff, and the study 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 study sponsor.

The study monitor or other authorized representatives of the NIDCR may inspect all study documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) for the study participants. The clinical study site will permit access to such records.

Certificate of Confidentiality

To further protect the privacy of study participants, the Secretary, Health and Human Services (HHS), has issued a Certificate of Confidentiality (CoC) to all researchers engaged in biomedical, behavioral, clinical, or other human subjects research funded wholly or in part by the federal government. Recipients of NIH funding for human subjects research are required to protect identifiable research information from forced disclosure per the terms of the NIH Policy (<https://humansubjects.nih.gov/coc/index>). As set forth in [45 CFR Part 75.303(a)](https://www.ecfr.gov/cgi-bin/text-idx?SID=f3e9328bbbd5aabe8e639ca48dcbcc7f&mc=true&node=se45.1.75_1303&rgn=div8) and [NIHGPS Chapter 8.3](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.3_management_systems_and_procedures.htm), recipients conducting NIH-supported research covered by this Policy are required to establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal statutes, regulations, and the terms and conditions of award. It is the NIH policy that investigators and others who have access to research records will not disclose identifying information except when the participant consents or in certain instances when federal, state, or local law or regulation requires disclosure. NIH expects investigators to inform research participants of the protections and the limits to protections provided by a Certificate issued by this Policy.

Confidentiality of Data Sharing

As described in section 16, it is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public (see <https://grants.nih.gov/policy/sharing.htm>). PIs and funding recipient institutions will ensure that all mechanisms used to share data include proper plans and safeguards to protect the rights and privacy of individuals who participate in NIH-sponsored research.

## Future Use of Stored Specimens and Other Identifiable Data

This pilot sttudy will not collect any samples. The NCC will create a de-identified Public Use Dataset that will be posted on the PBRN public website at the conclusion of the study. Identifiable data will remain within the NCC.

# DATA HANDLING AND RECORD KEEPING

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

## Data Management Responsibilities

The PIs in collaboration with the NCC will review reports of data completeness and accuracy as well as protocol compliance on an ongoing basis throughout the study. A statement reflecting the results of the review will be sent to the NIDCR in the annual report. Data quality will be assessed using measures such as time from study visit to data entry, time to resolution of data queries, number of missing forms, and proportion of all study variables queried. The process and timeline for review will be detailed in the study-specific Data Quality Management Plan.

## Data Capture Methods

Study-specific electronic questionnaires will be developed to include fields for all data elements and will be translated into electronic CRFs, which will be entered in a secure EDC system. Electronic CRFs will be used to obtain data from participating practitioners and patients at each study visit. The NCC will conduct preliminary testing and review of data fields in the initial programming and online launch of the EDC. The NCC will ensure that all required data are collected per protocol requirements and edit checks will be programmed in the electronic CRFs to correct data issues in real time. The NC and NCC staff will respond to data queries generated by the EDC system to ensure correction of data errors. Reports or tools will be developed to help monitor the data capture activities, including checking data fields for completeness and accuracy. Summary reports of data completeness and accuracy will be made available to the study team and NIDCR as requested.

## Schedule and Content of Reports

Quality Control (QC) Reports: Regular QC reports will be available on the HUB for this study and will be viewable by the Study PI, their designates, NCs, the NCC Data Manager and the Study Manager.  These reports are intended to help the NCs review all data issues that may require follow-up with the practitioners or patients. Specific reports for incomplete forms and missing forms as well as reports where data may not have been completed in the correct sequence (e.g., schedule of assessments) will be generated. The NCs will use these reports to work with the practitioners to rectify any erroneous or incomplete data

Study Remote Monitoring Reports:  Standardized Study Remote Monitoring reports will be created and posted to the study module on the HUB. These reports contain summarized data on enrollment, retention, protocol deviations, etc.  These summary reports will be viewable by study team members, network staff, NCC staff and NIDCR.

## 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 NIH.

## Protocol Deviations

A protocol deviation is any change, divergence, or departure from the study procedures described in the IRB-approved clinical study protocol. The deviation may be on the part of the participant, the investigator, or study staff.

Consistent with the investigator obligations in the ICH E6 Guideline for Good Clinical Practice, ARC or NCC personnel will document in study source documents and explain any deviation from the IRB-approved protocol. Within 30 days of any protocol deviation, the PI will report to the IRB any deviations or changes made to eliminate immediate hazards to participants and any changes that increase risk to participants and/or significantly affect the conduct of the study.

Protocol deviations will be assessed for their impact on safety, study operations, and data integrity. Appropriate corrective and preventive actions will be implemented if warranted.

# PUBLICATION/DATA SHARING POLICY

This study will comply with all applicable NIH Data Sharing Policies. See <https://grants.nih.gov/policy/sharing.htm> for policies and resources.

NIH Public Access Policy

The NIH [*Public Access Policy*](https://publicaccess.nih.gov/index.htm) requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to [*PubMed Central*](https://www.ncbi.nlm.nih.gov/pmc/) immediately upon acceptance for publication. This ensures that the public has access to the published results of NIH funded research.

The Network’s “National Dental PBRNPublications, and Presentations Policy” document is available at the network’s public web site at <https://www.nationaldentalpbrn.org/publications/>.

APPENDIX A: Schedule of Events

**Practitioner Procedures**

|  |  |  |  |
| --- | --- | --- | --- |
| **Practitioner/Dental Hygienist/Dental Office Staff Procedures** | Dental Office Personnel Recruitment (includes dentist/hygienist/dental assistants/dental\office staff) |  Pilot Study (1-month) |  At the end of pilot study  |
| Study Information Sheet Sent to Dental Practice | x |  |  |
| Provider Pre-Study Survey (prior to patient recruitment) | x |  |  |
| Study Procedures Training  | x | x |   |
| Patient Recruitment/ Consecutive Eligible Patient Enrollment Log (Approximately 1 month) |  | x |  |
| Provider Post-Patient Survey(Within 24 hours after each patient’s visit) |  | x |  |
| Provider Post-Study Survey (Approximately 2 weeks after all subject visits are completed)  |  |  | x |

**Patient Procedures**

|  |  |  |  |
| --- | --- | --- | --- |
| **Patient Procedures (approximately 1 month total duration)** | At Beginning of Dental Visit | Dental Visit  | Following Dental Visit (Approximately 1 week following visit) |
| Complete Consent Form  | X |  |  |
| Patient Demographics Survey  |  | X |  |
| Patient Contact Form |  | X |  |
| Mental Health Screening Forms (PHQ-2, GAD-2, CAGE-AID, C-SSRS)  |  | X |  |
| Patient Post-Visit Survey(Approximately 1 week post-visit)  |  |  | X |

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