

National Dental PBRN COVID-19 REsearch (CORE) Registry

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
STATEMENT OF COMPLIANCE

The study will be conducted in accordance with the International Council for Harmonization 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

practice facility and equipment (FAC); practitioner and staff (STAFF); Office Visits (VISIT)

ADA	American Dental Association
ADHA	American Dental Hygiene Association
AE	Adverse Event/Adverse Experience
ASTDD	Association of State and Territorial Dental Directors
CART	Classification and Regression Tree
CDC	US Centers for Disease Control and Prevention
CE	Continuing Education
CFR	Code of Federal Regulations
CORE	National Dental PBRN COVID-19 Research
COVID-19	Coronavirus Disease 2019
CROMS	Clinical Research Operations and Management Support
CRQ1	CORE Registry Questionnaire Wave 1
CRQ2	CORE Registry Questionnaire Wave 2
CRR1	CORE Registry Results Report Wave 1
CRR2	CORE Registry Results Report Wave 2
CRW1	CORE Registry Results Webinar Wave 1
CRW2	CORE Registry Results Webinar Wave 2
CSI	Clinical Site Investigator
EDC	Electronic Data Capture System
FAC	Facility and equipment measures
DHHS	Department of Health and Human Services
FFR	Federal Financial Report
FWA	Federal wide Assurance
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
ICF	Informed Consent Form
ICH	International Council for Harmonization
IRB	Institutional Review Board
N	Number (typically refers to participants)

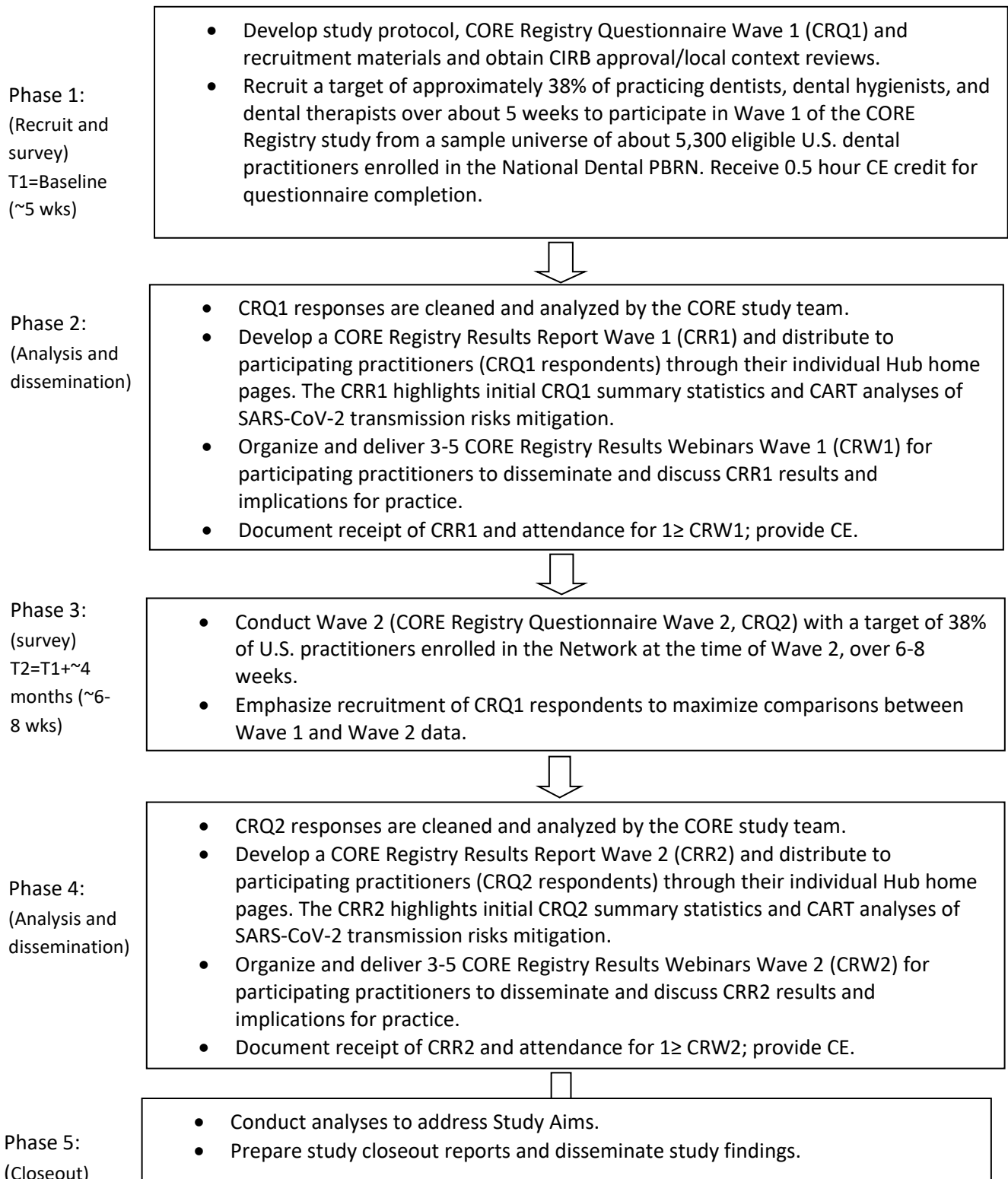
NC	Node Coordinator
NCC	Network Coordinating Center
NIDCR	National Institute of Dental and Craniofacial Research, NIH, DHHS
NIH	National Institutes of Health
OCTOM	Office of Clinical Trials Operations and Management, NIDCR, NIH
OHRP	Office for Human Research Protections
OHSR	Office of Human Subjects Research
OSAP	Organization for Safety, Asepsis, and Prevention
OSHA	Occupational Safety and Health Administration
P2P	Patient-to-patient
P2S	Patient-to-staff
PD	Protocol Deviation
PHI	Private Health Information
PI	Principal Investigator
PID	Practitioner Identification Number
PO	Program Official, NIDCR, NIH
PPE	Personal Protective Equipment
PS	Project Scientist, NIDCR, NIH
QA	Quality Assurance
QC	Quality Control
RCT	Randomized Clinical Trial
S2P	Staff-to-patient
S2S	Staff-to-staff
SAE	Serious Adverse Event/Serious Adverse Experience
SC2	Novel coronavirus SARS-CoV-2
SOP	Standard Operating Procedure
STAFF	Practitioner and staff measures
UP	Unanticipated Problem
US	United States
VA	Department of Veterans Affairs
VISIT	Office visit measures
WHO	World Health Organization

PROTOCOL SUMMARY

- Title:** National Dental PBRN COVID-19 REsearch (CORE) Registry
- Précis:** This study establishes a National Dental PBRN **COVID-19 Research (CORE) Registry** to support multilevel intervention and implementation science research on topics that are important to dental practitioners that include factors at the environmental, organizational, and/or individual level. We will recruit about 38% of active National Dental PBRN practitioners to participate in the CORE Registry study. The CORE Registry seeks to identify and evaluate the approaches used by National Dental PBRN practitioners to mitigate SARS-CoV-2 (SC2) transmission risks at dental offices. Mitigation costs and practitioners' comfort levels with infection control practice guidelines and mitigation approaches will also be assessed. Differences in mitigation approaches, costs, and comfort levels associated with practice and practitioner characteristics will be evaluated.
- Objectives and Outcome Measures:** The primary objective of the proposed CORE Registry is to identify and compare the use of recommended approaches among National Dental PBRN practitioners to mitigate SARS-CoV-2 transmission risks at dental offices, by transmission pathway and mitigation type.
- There are four secondary outcome measures: 1) total and monthly expenditures for mitigation; 2) level of comfort/confidence with guidelines and mitigation approaches used; 3) changes in mitigation approach, costs, and comfort/confidence between Wave 1 and Wave 2 questionnaires; and 4) successful integration of a COVID-related X01 study.
- Population:** Eligible U.S. dental practitioners (dentists, dental hygienists, and dental therapists) who are enrolled in the National Dental PBRN at the time of survey recruitment and provide patient care at least one day per week.
- Number of Sites:** The study includes six regional nodes, the specialty node, and is led by researchers at the National Coordinating Center.
- Study Duration:** 12 months (9/01/2020 – 8/31/2021)

Subject Participation Duration:	Eligible practitioners participating in all study events can be involved in research activities for approximately 10 months.
Estimated Time to Complete Enrollment:	Initial study enrollment, i.e., completion of CORE Registry Questionnaire 1 (1 st Wave) will span approximately 5 weeks. Completion of Wave 2 of the Questionnaire will occur over approximately 6-8 weeks.

Schematic of CORE Registry Study Design:



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2. INTRODUCTION: BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

2.1 . Background Information

The global spread of the novel coronavirus SARS-CoV-2 (SC2) has led to over 7 million cases of COVID-19, the disease caused by the coronavirus, and over 200,000 deaths in the United States.(1) The pandemic has severely impacted healthcare delivery systems, economic activity, and social relationships. As the pandemic evolved, COVID-19 resulted in significant challenges for dental offices to keep the needed personal protective equipment (PPE) in stock. Beginning in March 2020, most state and federal agencies requested that elective medical and dental care be deferred due to fears of the virus spreading. Most dental offices limited services to emergency care, some closed entirely. Beginning in late April, states began allowing dental offices to reopen for routine care services, even though incidence of COVID-19 and related deaths were increasing in many states and counties.(1)

Many dental procedures generate substantial aerosols and there are many different methods that dental practitioners and organizations can use to limit aerosol creation and fomite contamination.(2-4) These methods can include modifications to facilities, patient flow, dental procedures and delivery methods, and use of personal protective equipment (PPE). Public health agencies and professional organizations continue to publish new practice recommendations for dental care and can be expected to continue issuing new guidelines as more is learned about SC2 transmission and COVID-19 symptoms and pathogenesis.(4-6) However, OSHA has yet to issue new practice standards and regulations, and practice guidelines have left practitioners to decide whether and how they adopt their practices. There is an urgent need among dental practices to identify and adopt measures that are effective in preventing SC2 transmission. A newly published study by the American Dental Association indicates that about 35% of dentists surveyed had not reopened for elective care, with one-third reporting unclear guidance as the reason.(7)

2.2 Rationale

This study establishes a National Dental PBRN COVID-19 REsearch (CORE) Registry to support multilevel intervention and implementation science research on topics that are important to dental practitioners. Multilevel research addresses topics, such as health care delivery, that involve environmental, organizational, and/or individual-level determinants.(8-10) The objectives of the proposed CORE Registry are to: a) identify common recommended approaches used by National Dental PBRN practitioners to mitigate SC2 transmission risks, their costs; assess practitioners' comfort levels with infection control information and mitigation approaches used in their dental offices; c) disseminate and discuss effective combinations of mitigation methods with participating practitioners and evaluate the impacts of these activities on the use of effective mitigation approaches and comfort levels; and d) establish a modular infrastructure to support the design and conduct of additional multilevel clinical and

implementation science research. We will evaluate SC2 mitigation methods and practitioner-reported comfort levels by practice setting, location, and specialty. The prospective standardized data collection proposed for the initial modules of the CORE Registry will provide the ongoing capacity to evaluate the impacts SC2 on dental practice and patient care, and to identify and assess needed adaptations to operations and physical layout across a national cohort of oral healthcare practitioners. Additional registry modules will support future clinical and implementation research such as in-office virus testing and contact tracing strategies, vaccine delivery, and patient-focused interventions.

Setting: The CORE Registry study will be conducted in partnership with the National Dental PBRN. 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.(11,12) 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 (13), and change practice patterns of participating dentists.(14,15) Data indicate that enrolled Network practitioners are similar to the general US dental provider population.(16)

There are about 8,000 U.S. dental practitioners, office staff, and researchers currently enrolled in the Network. As of September 15, 2020, there were nearly 5,300 active practitioners in the Network who provide patient care and were enrolled as full or limited participation. While enrollment and participation levels vary somewhat by region, every U.S. state is represented. Most enrolled dentists practice general dentistry, with dental specialists accounting for about 25% of total enrollment.

2.3 Potential Risks and Benefits

Two practitioner questionnaires will be sent via email link to all U.S. active dental practitioners enrolled in the network at the time of recruitment, followed by Rapid Results reports sent to participating practitioners and results report informational webinars conducted after each questionnaire.

In each questionnaire, **participating practitioners are to record the number of dental office staff (separately for practitioners and non-clinical office staff) that has test positive for COVID-19 disease or has had symptoms. While the numbers reported may not be PHI, since dates and other individually identifiable information are not provided, there may be small practices with few clinical and/or non-clinical staff members who report COVID incidence. In order to protect participant and staff confidentiality, we will treat any reported COVID incidence**

among participants and staff as PHI and apply CIRB-approved and HIPAA compliant processes to limit access and protect confidentiality of these data.

2.3.1 Potential Risks

This study poses no more than minimal risk to study participants. Study participation is completely voluntary, and participants may discontinue participation at any time without penalty or negative consequences. The primary potential risk to practitioners is the potential for loss of confidentiality of survey responses; however, appropriate precautions will be taken to mitigate this risk. Unique study codes will be used for participants and National Coordinating Center (NCC) standards will be followed to secure participant data collected through Redcap and stored on NCC secure filesystems. Compliance with all Institutional Review Board (IRB) regulations concerning data collection, data analysis, data storage, and data destruction will be strictly observed.

2.3.2 Potential Benefits

Study participants may directly benefit from receiving study results following completion of each questionnaire and from attending study webinars. The research results may help practitioners identify and better understand alternative approaches to mitigate SARS-CoV-2 transmission at dental offices and during patient care. 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 to oral health researchers, policymakers, professional associations, and insurers.

3. OBJECTIVES AND OUTCOME MEASURES

3.1 Primary

Objective	Brief Description/ Justification of Outcome Measure	Outcome Measured By	Time Frame
<p>Primary objective 1. Identify and compare the use of recommended approaches among National Dental PBRN practitioners to mitigate SARS-CoV-2 transmission risks at dental offices, by transmission pathway and mitigation type.</p>	<p>Practitioners may use different recommended approaches to mitigate transmission risks. Little is known about the combinations of mitigation approaches used by dental practitioners.</p> <p>Sources for recommended mitigation approaches include OSHA, CDC, WHO, state health departments, or other policy making bodies. Recommendations are also provided by professional societies (e.g., ADA, ADHA) academic centers, and other public health organizations.</p> <p>These approaches can be classified by mitigation type: facility or equipment modifications; office visit management and patient flow, including procedures and PPE use; and office staffing.</p> <p>Transmission risks can be classified as patient-to-staff (P2S), staff-to-patient (S2P), staff-to-staff (S2S), patient-to-patient (P2P), or some combination of each.</p>	<p>Survey questions will address mitigation approaches within each of the mitigation type and transmission pathway domains. The surveys are divided into sections: 1) External environment, 2) practice/organization, 3) office visit, 4) individual practitioner and staff, 5) financial costs.</p> <p>Each survey question response is classified as either dichotomous (yes/no) or ordered by frequency of performance (e.g., always, almost always, and other).</p>	<p>Data are collected from 2 practitioner surveys ~6-8 months apart.</p> <p>Current practice guidelines are collected at two time points that correspond to the release of the survey waves.</p>

3.2 Secondary

Objectives	Brief Description/Justification of Outcome Measure	Outcome Measured By	Time Frame

<p>1. Secondary objective 1:- Estimate mean total fixed and monthly expenditures to mitigate SARS-CoV-2 transmission risk, overall and for mutually exclusive groups of practitioners identified by the primary objective analysis</p> <p>2. Secondary objective 2: Assess mean levels of comfort and/or confidence with available information and guidelines for infection control, approaches used to mitigate SARS-CoV-2 transmission risks, and the financial impact of mitigation, overall and for mutually exclusive groups of practitioners identified by the primary and secondary objective analyses</p> <p>3. Secondary objective 3: Disseminate the Wave 1 Rapid Report and conduct informational Rapid Report Webinars with network practitioners, and assess the impacts of Report dissemination on changes in practitioners' mitigation approaches, mitigation costs, and comfort levels, overall and for different practitioner subgroups</p> <p>4. Secondary objective 4: Establish a modular infrastructure to support the design and conduct of additional multilevel clinical and implementation science research.</p>	<p>1. The cost to dental practices for coronavirus mitigation may be significant and may influence the approaches used by practitioners and practices. PPE and other mitigation costs will be obtained via the financial costs section of the survey</p> <p>2. Dental care delivery creates aerosols as part of routine service delivery. Practitioner's level of comfort with treating patients with known or asymptomatic COVID-19 is an important concern that may affect their mitigation choices.</p> <p>3. This study involves practitioners in the study by incorporating Rapid Results reporting and informational webinar attendance following each wave of the questionnaire. This provides an opportunity for participants to gain knowledge quickly in a rapidly changing environment, which may impact the mitigation approaches they use. We will provide Rapid Report results using the practitioner's page in the Hub, and schedule webinars to enhance discussion and support peer-to-peer information sharing. We will compare Wave 1 and Wave 2 responses to assess the impacts of the reports and webinar attendance on changes in mitigation approaches</p> <p>4. The CORE Registry programming and data collection capabilities will be developed to support the additional of new modules</p>	<p>1. Cost measures include practitioner-reported mean mitigation costs for practice and office visit approaches to SC2 transmission risk mitigation. Mean reported expenditures on SC2 mitigation strategies for facility modification, equipment, and PPE use.</p> <p>2. Mean comfort and/or confidence levels are estimated for each surveyed mitigation approach using 5-point Likert scales</p> <p>3. Changes in virus mitigation approaches (Aim 3) are assessed by comparing Wave 2 with Wave 1 data for practitioners who complete both surveys. Wave 2 survey includes questions for assessing the impact of Rapid Reports and webinars from Wave 1 on practitioner decision making.</p> <p>Changes in comfort levels are also assessed, which is relevant for respondents who may not</p>	<p>1-3. Data are collected from 2 practitioner surveys. Practice recommendations and guidelines, and disease incidence data are collected at the time of each survey conduct.</p> <p>4. Capability for expansion is designed into the Registry as the CORE Registry study modules are built. Integration of at least one COVID-related network study will be assessed by 2 years after completion of the CORE study.</p>
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	<p>that may be developed for implementation depending on approved research studies and resources.</p> <p>Potential future modules include: a) an SARS-CoV-2 Reporting “Dashboard” and Risk Assessment Tool and Network practitioners; b) COVID-19 antigen/antibody testing and contact tracing research; c) Dental office staff and patient vaccination research; d) Interventions to reduce COVID-19 transmission risks; and e) Patient COVID-19 history, knowledge and mitigation practices research.</p>	<p>change their mitigation approach but may have improved confidence in the approaches they use. These would otherwise go unmeasured.</p> <p>4. Aim 4 outcome measured as the successful integration of one or more additional COVID-related network study.</p>	
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4. STUDY DESIGN

The CORE Registry study is a cross-sectional survey administered at two time points, with comparison of response changes between the two survey periods. The study includes: a) administration of a CORE Registry Questionnaire in two waves; b) identification of common approaches used by National Dental PBRN practitioners to mitigate SARS-CoV-2 transmission risks, their costs, and assess practitioners' comfort levels with these approaches; and c) rapid reporting of survey results after each wave using research summary reports and informational webinars. Classification and Regression Tree (CART) techniques will be used to assess practitioner type, practice setting, location, and other factors associated with differences in mitigation methods, costs, and comfort levels for Waves 1 and 2, and changes between each wave.

All eligible dental practitioners at the limited or full participation level in the National Dental PBRN will be invited via email to participate in the CORE Registry study. The surveys will be administered using the electronic data capture (EDC) system on the Network HUB website, housed at the NCC.

5. STUDY POPULATION

We plan to recruit a target of approximately 38 percent of all active U.S dental practitioners (dentists, dental hygienists and dental therapists) who are enrolled in the National Dental PBRN at the time of recruitment. There are currently about 5300 active U.S. practitioners who are eligible to participate.

5.1 Participant Inclusion Criteria

To be eligible to participate in this study, a practitioner must meet the following criteria:

- Be enrolled in the National Dental PBRN during the survey recruitment periods.
- Is a current limited or full participation member of the National Dental PBRN (EQ Qx 7).
- Is a currently practicing dentist, dental hygienist, or dental therapist in the US (EQ Qx 1: response categories 1-12).
- Has current contact information on file at which he or she can be contacted (EQ contact information).
- Be able to receive emails and access online questionnaires

5.2 Participant Exclusion Criteria

Practitioners are excluded from the study if they:

- Are a graduate student, intern or resident, dental student, dental hygiene student, dental therapy student as indicated on the Enrollment Questionnaire.

5.3 Strategies for Recruitment and Retention

Recruitment

The CORE Registry Questionnaire Wave 1 (CRQ1) will include all U.S. practicing dentists, dental hygienists, and dental therapists who are enrolled in the network during a target 5-week enrollment period. CORE Registry Questionnaire Wave 2 (CRQ2) will have the same eligibility criteria used in Wave 1 during a target 6-8 weeks enrollment period.

The enrollment periods are targets and may be extended if needed to meet the study's planned enrollment targets.

Recruitment will be conducted through centralized emails and other outreach from the NCC followed by Regional Node Coordinator outreach. NCs will use locally defined outreach processes, which include but are not limited to targeted emails and phone calls. Node Coordinators (NCs) will document approaches used and report these to the study team.

Eligible practitioners will be recruited through centralized emails with embedded links to the Wave 1 or Wave 2 questionnaires. The NCC will send an initial email and a planned two follow-up emails with the survey link to all eligible practitioners.

Separate, tailored follow-up emails will be sent to non-respondents and respondents who initiated but not completed the questionnaire. The first reminder email to each group also will include an offer to attend a brief informational recruitment video webinar to learn more about the study objectives, activities, and timeline of events, and to ask questions.

If initial NCC-led recruitment rates are substantially lower than expected, the study team and NCC may conduct additional recruitment activities to bolster participation rates, including informational video webinars, outreach via network social media accounts, and additional tailored emails to practitioner groups in settings, locations and demographic groups that are below target participation levels.

After centralized recruitment activities are completed, the NCC will prepare a list of non-responders and participants with incomplete information for each regional node and place the lists on the Hub for NCs for regional follow-up. NCs may use targeted emails, telephone calls, and other methods as determined by each node. Recruitment reports will be reviewed by the study team and Node Coordinators to assess progress, lessons learned, identify successful outreach methods. Node Coordinators may also contact participants as part of data cleaning conducted by the NCC.

We will recruit a target 38% of non-Hispanic white and Asian practitioners, groups that are well-represented in the network. We plan to enroll a target of 45% for under-represented minority (URM) practitioners, including Hispanic/Latinos, Black/African Americans, Alaska Native and Native Americans, and Native Hawaiian/Pacific Islanders, multi-race, and others. We will include race-ethnicity recruitment rates in our reports and use tailored follow-up emails to help promote URM recruitment and include these data in reports for regional NCs.

Participant Incentives

We do not plan to provide financial remuneration for study participants. While we provide no monetary remuneration, we believe the importance of the topic and the inclusion of rapid reporting and webinars for participating practitioners will drive recruitment. Additionally, respondents who request Continuing Education credit by answering affirmatively to the last question in the CRQ1 will receive 0.5 hour CE credit

from the UAB School of Dentistry Continuing Education Department. Depending on available resources, CE Credit for completing the last question in the CRQ2 survey may also be provided.

Participating practitioners will receive Wave 1 and Wave 2 CORE Registry Rapid Reports (CRR1 and CRR2) and encouragement to attend CORE Registry Study results webinars.

Practitioners attending a CORE Registry Results Webinar (CRW1 or CRW2) may receive 1.0 CE credit from the UAB School of Dentistry Continuing Education Department for each hour of webinar attendance.

In addition, depending on analyses of Wave 1 results, the study team may decide to conduct a test-retest process for a small sample of Wave 2 questionnaire completers. We expect a retest would include a target of approximately 20-40 (max of 60) participants.

5.4 Participant Withdrawal

Practitioners who contact network staff requesting withdrawal from further CORE Registry activities will be placed on a do not contact list and removed from study-related email communications.

5.4.1 *Reasons for Participant Withdrawal*

The NCC and NC staff will make reasonable efforts to determine reasons for study withdrawal and report results to the NCC and study team.

5.4.2 *Handling of Participant Withdrawals*

The study team and NCC staff will create and maintain a list of practitioners who request withdrawal from further CORE Registry study activities. These numbers will be included in recruitment results reporting.

It is anticipated that participants will not be replaced.

5.5 Premature Termination or Suspension of Study

This study may be suspended or prematurely terminated if there is sufficient reasonable cause. The SPI 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.

6. STUDY SCHEDULE

The CORE Registry study is conducted in five (5) phases over an approximate 12-month period.

6.1 Phase 1 – CORE Registry Questionnaire Wave 1 (CRQ1) and CRQ1 practitioner recruitment launch (T1 = Baseline + ~5 weeks)

- Recruit a target of approximately 38% of practicing dentists and hygienists over about 5 weeks to participate in Wave 1 of the CORE Registry study from a sample universe of all eligible U.S. dental practitioners enrolled in the National Dental PBRN.
- We expect enrollment to increase during the study period as new practitioners are continually recruited to the network, so the specific enrollment targets and target achievement will be defined at the time of CRQ1 launch.

6.2 Phase 2 – CRQ1 analysis and initial result dissemination

- CRQ1 responses are cleaned and analyzed by the CORE study team.
- Develop a CORE Registry Results Report Wave 1 (CRR1) and distribute to participating practitioners (CRQ1 respondents) through their individual Hub home pages. The CRR1 highlights initial CRQ1 summary statistics and CART analyses of SARS-CoV-2 transmission risks mitigation.
- Organize and deliver 3-5 CRR1 webinars (CRW1) for participating practitioners to disseminate and discuss CRR1 results and implications for practice. Webinar schedules will be developed in consultation with NCC and ARC staff. Webinar recruitment emails will be sent centrally by the NCC and regional NCs.
- Document receipt of CRR1 and attendance for 1≥ CRW1; provide CE for attendees.

6.3 Phase 3 – Conduct CORE Registry Questionnaire Wave 2 (CRQ2) (T2 = T1 + ~4 months (+~6-8 weeks))

- Conduct Wave 2 (CORE Registry Questionnaire Wave 2, CRQ2) with a target of 38% of U.S. dentists and hygienists enrolled in the Network at the time of Wave 2, over 6-8 weeks.
- Emphasize recruitment of CRQ1 respondents to maximize comparisons between Wave 1 and Wave 2 data.

6.4 Phase 4 – CRQ1 analysis and results dissemination for practitioners

- CRQ2 responses are cleaned and analyzed by the CORE study team
- Develop a CORE Registry Results Report Wave 2 (CRR2) and distribute to participating practitioners (CRQ2 respondents) through their individual Hub home pages. The CRR2 highlights initial CRQ2 summary statistics and CART analyses of SARS-CoV-2 transmission risks mitigation
- Organize and deliver 3-5 CRR2 webinars (CRW2) for participating practitioners to disseminate and discuss CRR2 results and implications for practice. Webinar recruitment emails will be sent centrally by the NCC and regional NCs.
- Document receipt of CRR2 and attendance for 1≥ CRW2; provide CE

6.5 Phase 5 – Study closeout and results reporting/dissemination

- Complete analyses to address study objectives

7. STUDY PROCEDURES/EVALUATIONS

Questionnaire Development

The primary sources of information used to develop the Wave 1 survey include the CDC's interim and updated guidance for infection prevention and control for healthcare personnel, and guidance for dental facilities and staff, the American Dental Association Health Policy Institute recommendations and scientific webinars, OSHA guidelines, and the Organization for Safety, Asepsis, and Prevention (OSAP) in partnership with DentaQuest.

Drafts of the survey questions, responses, and content flow were developed by the study team and reviewed by NIDCR, the Data Committee, the Biostat Core, and Practitioner Executive Committee prior to finalizing the survey instrument. As part of the review process, the survey instrument was assessed to ensure it is psychometrically sound and to ensure the data collected will allow for adequate evaluation of study objectives.

The Wave 2 survey repeats survey items from Wave 1 and includes additional items to assess participant receipt of the Wave 1 Rapid Report, Wave 1 webinar attendance, and impacts of these activities on SC2 mitigation approaches and comfort levels. Depending on scientific development and guidelines related to SC2 transmission risks, some individual survey items or responses may be revised.

The Wave 2 survey will undergo the review process described above for the Wave 1 survey.

Questionnaire User Testing

The NCC will perform internal testing of the electronic study questionnaire and include testing internet browser compatibility. Study team members (e.g. PI, National Network Director, Node Directors, etc.) will be given the opportunity to externally test the website prior to administration to study participants.

Questionnaire Administration

Eligible participants will be identified from their responses to the network's enrollment questionnaire.

A waiver of documentation of signed informed consent for participants who complete the electronic questionnaire will be requested. Consistent with regulations outlined by the University of Alabama at Birmingham IRB and regional/local IRBs, information about the study will be provided to all eligible participants in the initial email invitation regarding the upcoming invitation to participate in the study. Completion of the questionnaire will indicate tacit consent.

After the initial invitation and 2 follow-up email reminders, the NCC will provide the NCs with a list of non-responders. The NCs will systematically contact non-responders to encourage questionnaire completion. If no feedback is received or the participant does

not complete the questionnaire after follow-up attempts over a period of up to three months, it will be assumed the practitioner is not interested in the study.

Cognitive Interviewing

Cognitive testing of the survey instrument was completed, in which dentists reviewed their responses to a completed survey and were probed to assess possible respondent problems in understanding questions, recalling necessary information, and/or reporting information accurately.

Questionnaire Testing-Retesting

User testing may also include test-retests of survey questions by survey participants. Test-retest may be performed for the Wave 2 questionnaire if warranted after analyses of Wave 1 results.

8. ASSESSMENT OF SAFETY

8.1 Definitions of Safety Parameters

8.1.1 *Unanticipated Problems*

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

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

8.2 Specification of Safety Parameters

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

8.3 Reporting Procedures

8.3.1 *Unanticipated Problem Reporting*

Per National Dental PBRN procedures, unanticipated incidents and events will be reported to the PI. After the PI 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 will be reported to the IRB as soon as possible but in all cases 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

9. STUDY OVERSIGHT

The PI 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 PI with current data summaries, and the PI 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 PI, NCC, and study team will adhere to data quality management processes (please see Section 13).

10. CLINICAL SITE MONITORING

No outside clinical site monitoring will be employed for this study. The NCC is responsible for launching the study and collecting data received as part of the study. Quality Assurance/Quality Control activities associated with data collection and processing will be developed by the NCC. The NCC will ensure that the quality and integrity of the study data and data collection are maintained. The NIDCR reserves the right to conduct independent clinical site monitoring as necessary.

11. STATISTICAL CONSIDERATIONS

11.1 Study Hypotheses

This is an observational study that has both cross-sectional and longitudinal components. The study objectives do not include testing specific hypotheses, but rather identifying groups of practitioners using recommended approach to mitigate coronavirus transmission risks in dental offices.

Sample Size Considerations

For the CORE Registry study, we seek to enroll about 38% of eligible U.S. practitioners in the National Dental PBRN, which includes a target of about 45% of under-represented minority practitioners in the network.

Sample size and power for primary outcome. The primary objective is to identify mutually exclusive combinations of approaches practitioners use to mitigate SARS-CoV-2 transmission risks at dental offices, and practitioner characteristics associated with differences between these combinations of approaches.

A recruitment and analysis plan has been developed that provides 80% power to detect significant differences between groups, assuming a two-tailed alpha level of .05 and accounting for intraclass correlations. It is expected that a large (about 2,000) and diverse sample of Network practitioners will participate in the study. In addition, use of CART modeling will enable evaluation of subgroups of variables with as few as 10-15 observations.(17,18) There are a limited number of covariates in the analysis plans, such as practice location (region/state), practice setting (solo, large group, academic, community/public health), practice type (general dentist, dental specialty, dental hygienist, dental therapist), and practitioner characteristics (years since dental school graduation, race-ethnicity, gender, etc.). Sub-group comparisons of some URM participants will be challenging given the current enrollment in the network.

Recruitment for the Wave 2 questionnaire (CRQ2) will be focused on practitioners who participated in Wave 1 (CRQ1) to support analyses of differences.

11.2 Final Analysis Plan

Two surveys of National Dental PBRN practitioners will be conducted to identify the approaches that practitioners and practices use to mitigate the risks of SC2 transmission for patients and dental office staff. The two surveys also collect information about sources of information and guidelines relevant to coronavirus risks and risk mitigation, practitioner-reported expenditures for mitigation (one time and recurring and monthly expenditures), weekly work hours and patient volume, and comfort or confidence levels with risk mitigation approaches and safe practice recommendations.

Participants and data.

In addition to survey data, the study team collects information on relevant practice guidelines and epidemiologic data from national and state sources, and practitioner information from the National Dental PBRN Enrollment Questionnaire (EQ).

EQ data includes practice location (region/state/county), practice setting (solo, large group, academic, community/public health), practice type (general dentist, dental specialty, dental hygienist, dental therapist), and practitioner characteristics (age, years since dental school graduation, race-ethnicity, gender, etc.).

Study measures. For this study, we separate SC2 transmission risks for dental care into four types (pathways): patient-to-staff (P2S); patient-to-patient (P2P); staff-to-patient (S2P); and staff-to-staff (S2S). Different risk mitigation approaches may address one or more pathway, but not every approach can address each pathway. We also group SC2 risk mitigation approaches into one of four categories (or types): practice facility and equipment (FAC); practitioner and staff (STAFF); Office Visits (VISIT) including patient flow and dental procedures; and personal protective equipment (PPE).

Practice-level (FAC) modifications include facility and equipment changes, patient flow redesign, and surface disinfectant procedures. Practitioner and staff (STAFF) modifications include workforce changes in hours worked and patient volume, and personnel measures to reduce or manage coronavirus exposure. Office visit (VISIT) modifications include changes to patient screening for COVID-19 and changes to aerosol generating dental procedures and techniques used. We also collect information on PPE use during dental and dental hygiene procedures, and access to PPE supplies.

We use published information obtained from the CDC, ADA, OSHA, and other sources to assign each approach to a pathway and category, noting that individual approaches may apply to more than one transmission pathway.

The primary outcome measure is individual and grouped practitioner-reported mitigation approaches. There are four secondary outcome measures: 1) total and monthly expenditures for mitigation; 2) level of comfort/confidence with guidelines and mitigation approaches used; 3) changes in mitigation approach, costs, and comfort/confidence between Wave 1 and Wave 2 questionnaires; and 4) successful integration of a COVID-related X01 study.

Addressing study Objectives. *Objective 1 (Primary). Identify and compare the use of recommended approaches among National Dental PBRN practitioners to mitigate SARS-CoV-2 transmission risks at dental offices, by transmission pathway and mitigation type.*

We will use data from the two surveys to identify distinct combinations of risk mitigation approaches, by type and transmission pathway, used by National Dental PBRN practitioners, overall and for different practitioner subgroups. First, we will examine the frequencies of individual approaches by type and pathway, that are reported by distinct groups of practitioners. We will use these results to inform a process to combine approaches within each type and pathway among subgroups of practitioners.

For the Wave 1 questionnaire, mitigation approaches reported by participating practitioners are grouped by approach type and transmission pathway. For each type and pathway, responses to individual approach questions are classified as either dichotomous (yes/no) or ordered by frequency of performance on a 5-point Likert scale. While responses to each approach will be examined individually, we expect to grade responses as “following practice guidelines” for an individual recommended approach that has a “yes” or “always” response. If warranted, we will also consider adding the “almost always” as a following practice guidelines response. The outcome measure analyses are represented by the following individual and group level assessment of mitigation approaches:

Ind: Approach i,p,t , = f(practice setting, practice type, practice location, guideline source and last review, practitioner demographics, COVID history, mitigation costs, work hours, patient volume)

Grouped: Rec Approach i,p,t , = f(practice setting, practice type, practice location, guideline source and last review, practitioner demographics, COVID-19 history, mitigation costs, work hours, patient volume)

where i = individual approach, p = pathway, and t =approach type; and Rec Approach is a dichotomous (yes/no) variable for each approach recommended that is followed, indicated as “yes” or “always”, by type and pathway. A yes to all recommendations receives a score of “1” and all other combinations receive a “0.”

First, we will examine the frequencies of individual approaches by type and pathway, that are reported by distinct groups of practitioners. We use these results to inform a process to combine approaches within each type and pathway among subgroups of practitioners. We will use CART analyses to identify distinct and mutually exclusive groups of practitioners using common sets of recommended mitigation approaches.

The grouped level analysis is speculative. We will compare the correspondence with the group-level model results with individual-level model results using appropriate statistical methods.

Objective 1 (secondary). Estimate mean total fixed and monthly expenditures to mitigate SARS-CoV-2 transmission risk, overall and for mutually exclusive groups of practitioners identified by the primary objective analysis

We will estimate mean reported total and monthly recurring expenditures and 95% confidence intervals for SC2 mitigation approaches, overall and by type (FAC, STAFF, VISIT, PPE) and pathway (P2S, S2P, S2S, P2P). We will then evaluate mean expenditures and CIs for groups of practitioners identified in Objective 1.

Objective 2 (secondary): Assess mean levels of comfort and/or confidence with available information and guidelines for infection control, approaches used to mitigate SARS-CoV-2 transmission risks, and the financial impact of mitigation, overall and for mutually exclusive groups of practitioners identified by the primary and secondary objective analyses.

We use 5-point Likert scales to estimate practitioners' mean comfort and/or confidence levels for select mitigation guidelines, type, and pathway. We estimate mean comfort levels for each group of practitioners identified in the Objective 1 analysis.

Objective 3 (secondary): Disseminate the Wave 1 Rapid Report and conduct informational Rapid Report Webinars with network practitioners, and assess the impacts of Report dissemination on changes in practitioners' mitigation approaches, mitigation costs, and comfort levels, overall and for different practitioner subgroups

Changes in virus mitigation approaches will be assessed by comparing Wave 2 with Wave 1 data for practitioners who complete both surveys. Wave 2 survey includes questions for assessing the impact of Rapid Reports and webinars from Wave 1 on practitioner decision making.

Changes in comfort levels will also be assessed, which is relevant for respondents who may not change their mitigation approach but may have improved confidence in the approaches they use. These would otherwise go unmeasured. We will use CART analysis to separately identify mutually exclusive groups of practitioners with common overall levels of comfort with their existing risk mitigation approaches from Questionnaires 1 and 2, and practitioners who report changes in comfort levels between the two surveys.

Objective 4 (secondary): Establish a modular infrastructure to support the design and conduct of additional multilevel clinical and implementation science research.

We are enabling additional modules to be incorporated into the CORE Registry through NCC participation with newly funded study teams who are addressing COVID-related research topics. This will involve developing common measures, integrating study data into the Registry structure, and other activities as necessary given available resources. The survey data will support numerous additional analyses, which will be developed as time and resources allow.

The objective 4 outcome will be measured as the successful integration of one or more additional COVID-related network study. Capability for expansion is designed into the Registry as the CORE Registry study modules are built.

Missing data. Data from incomplete questionnaires may be included in data analyses. Depending on the extent of missing data and available resources for analyses, the study team may consider statistically appropriate methods for imputing missing information.

12. SOURCE DOCUMENTS AND ACCESS TO SOURCE DATA/DOCUMENTS

Source data/documents will be maintained by the NCC for this study. The NCC will program the electronic questionnaires into their EDC on the HUB website. Participants will be sent an email invitation with a direct link to the electronic questionnaire. After completion of the electronic questionnaire, data will be available through the EDC.

Only study personnel i.e. NCC, PI and designated study team members will have access to the data. All research computers and associated study documents will be password-protected and maintained in compliance with ICH E6, Section 4.9 and regulatory and institutional requirements for the protection of confidentiality of subjects. Study staff will permit authorized representatives of NIDCR and regulatory agencies to examine (and when required by applicable law, to copy) research records for the purposes of quality assurance reviews, audits, and evaluation of the study safety, progress and data validity.

The PI and designated study team members will create an MS Access database of federal, state, and professional dental practice and workplace regulations, and clinical practice guidelines and recommendations related to the mitigation of SARS-CoV-2 transmission risks at dental practice settings. The study team will maintain and periodically update the Access database. Through a partnership with ASTDD, the Study team will provide access to the Policy database to state dental directors.

The source documents for this study are:

- Electronic study questionnaire administered through the NCC EDC on the HUB website
- Selected data collected on the National Dental PBRN Enrollment Questionnaire (gender, year of birth, race/ethnicity, present practice type, year of dental school graduation, full time or part time practice, practice type (dentist, hygienist, dental therapist) and specialty general practitioner or specialist,)
- State and local epidemiologic data on COVID-19 incidence and hospitalization are obtained through publicly available sources, including the Johns Hopkins University COVID-19 Tracking Website and state and local departments of health.
- Federal, state, and professional society clinical practice guidelines and recommendations relevant to coronavirus transmission risk mitigation are

obtained from publicly available sources and maintained in an MS Access Database by the Study team and NCC for analysis purposes. Sources include the CDC, World Health Organization, American Dental and Dental Hygiene Associations, the Association of State and Territorial Dental Directors, and state dental associations. Applicable federal and state regulations are obtained from Occupational Safety and Health Administration, state departments of health, and state licensing boards.

13. QUALITY CONTROL AND QUALITY ASSURANCE

For the Quality Control (QC) and Quality Assurance (QA) activities associated with data collection and processing, procedures will be developed to include automatic data quality checks in the EDC for the questionnaire and the processes related to data accuracy and completeness. The EDC will be programmed with edit checks and response limiters to reduce data response errors.

14. ETHICS/PROTECTION OF HUMAN SUBJECTS

14.1 Ethical Standard

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

14.2 Institutional Review Board

The protocol, informed consent form(s), recruitment materials and all participant materials will be submitted to the National Dental PBRN Central Institutional Review Board (IRB) for review and approval. The UAB IRB for Human Use serves as the National Dental PBRN Central IRB. 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 IRB before the changes are implemented in the study.

For those study investigators requiring IRB approval by their institutions, the study institution PI will submit for IRB approval and provide the Central IRB with the appropriate approved IRB documents.

14.3 Informed Consent Process

A waiver of documentation of signed informed consent for practitioners who complete the electronic questionnaire will be requested. Consistent with regulations outlined by the National Dental PBRN Central IRB, information about the study will be provided to eligible practitioners in an initial study invitation email as well as in the electronic questionnaire prior to the start of the questionnaire. Initiation of the questionnaire will provide a record of tacit consent.

14.4 Exclusion of Women, Minorities, and Specific Age Groups

National Dental PBRN dentists of any age, sex/gender or racial/ethnic group may participate if they meet the eligibility criteria.

14.5 Participant Confidentiality

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

Practitioners' pre-assigned identification numbers (PIDs) (practitioner IDs assigned by the National Dental PBRN) will be used to maintain study records and organize data

files. A file linking participants' names with their unique identification number will be kept in a password-protected file by the NCC.

The study monitor or other authorized representatives of the NIDCR may inspect all study documents and records required to be maintained by the investigator.

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\(a\)](#) and [NIHGPS Chapter 8.3](#), 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.

15. DATA HANDLING AND RECORD KEEPING

The study team is responsible for ensuring the accuracy and completeness of the data reported, and for following the data collection procedures. Access to study data will be provided to study team members by NCC staff.

15.1 Data Management Responsibilities

The PI will work closely with the NCC to ensure that the electronic surveys 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 to monitor progress, manage study documentation and procedures, and troubleshoot any problems.

The NCC will develop and maintain an EDC system, including the study questionnaire and procedures that will be followed to launch and monitor the study. The data reported in the Network's Practitioner Database will be used by the NCC to identify eligible dentists for this study.

15.2 Data Capture Methods

Data from the electronic questionnaire will be captured using REDCap forms in the EDC. The NCC will conduct preliminary testing and review of data fields in the initial programming and online launch of the questionnaire. The NCC will ensure that all required data are collected per protocol requirements and edit checks will be programmed in the web questionnaire to correct data issues in real time. The study team will ensure that data fields in the system are checked for completeness and accuracy so data entered in the EDC can be validated and data errors corrected in real time. Reports or tools will be developed to help monitor the data capture activities. The reports with the summary of data completeness and accuracy will be made available to the study team and NIDCR as requested.

15.3 Schedule and Content of Reports

Ongoing reports to monitor enrollment will be produced monthly for study team and NIDCR review. The contents of the reports will include the summary of data collected and can be developed in separate sections by key characteristics or regions.

Final data analysis reports that address objectives of the study will be produced by the NCC for review by the study team and NIDCR. The content of these reports will be determined by the study team and the NCC and defined in the Statistical Analysis Standard Operating Procedure.

The procedure for locking the database prior to final analysis will be detailed in the study Data Management Plan. Briefly, the EDC data will be locked and final study datasets will be generated at the end of the study. Prior to locking the database, the NCC's Data Manager (DM) or designee will ensure all data are complete and clean as

determined by the study team. Then, the DM will obtain approval from the SPI to proceed with the data lock.

No masking or coding is anticipated for this study.

15.4 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 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. The file connecting subjects' names with their unique identification number will be kept in a password-protected file by the NCC and PI, in accordance with IRB regulations, before being securely erased on agreement by the ARC Director, the NCC Director, and the PI.

15.5 Protocol Deviations

A protocol deviation (PD) 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, the SPI will document in study source documents and explain any deviation from the IRB-approved protocol. The SPI 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.

16. 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* requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to *PubMed Central* 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 PBRN Publications, and Presentations Policy" document is available at the network's public web site at <https://www.nationaldentalpbrn.org/publications/> .

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