

Coronavirus Vaccine Acceptance and Readiness Among Dentists (CARAD)

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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

ADA	American Dental Association
ADHA	American Dental Hygiene Association
AE	Adverse Event/Adverse Experience
CART	Classification and Regression Tree
CDC	US Centers for Disease Control and Prevention
CE	Continuing Education
CFR	Code of Federal Regulations
COVID-19	Coronavirus Disease 2019
CROMS	Clinical Research Operations and Management Support
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
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
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

PROTOCOL SUMMARY

- Title:** Coronavirus Vaccine Acceptability and Readiness Among Dentists (CARAD)
- Précis:** This study uses a mixed-methods approach to evaluate factors affecting dental practitioners' willingness and readiness to provide or facilitate coronavirus and other vaccine delivery during dental office visits. We address study questions using qualitative interviews with a target of 30 dental practitioners from the Western Region of the National Dental PBRN. The qualitative data are used to inform a survey of about 500 National Dental PBRN practitioners to identify factors associated with practitioners' acceptance, hesitancy, and readiness to provide or facilitate delivery of coronavirus vaccines at dental office visits. Data from this study will provide valuable insights about willingness and ability to participate in a broad-based public health effort to vaccinate the US population against SARS-CoV-2 infection and other communicable diseases, including the impacts of legislative and supply management barriers.
- Objectives and Outcome Measures:** The objectives of the proposed study include:
1. Analyze the acceptability, appropriateness, and feasibility of adopting COVID-19 and other vaccine delivery programs among dental practitioners with and without existing vaccine program experience, by practice type, setting, and location.
 2. Assess levels of acceptability and readiness to participate in alternative COVID-19 vaccine delivery programs, and other vaccine programs, through dental offices, by practitioner and practice characteristics, and accounting for relevant vaccine supply management and legislative factors
- Population:** Practitioners enrolled in the National Dental PBRN at Level 2 (limited) or Level 3 (full) participation, an active practitioner licensed to practice in the US.
- Number of Sites:** The qualitative component of the study will be conducted with dental practitioners enrolled in the Western Node of the National Dental Practice-Based Research Network (Network). The questionnaire study includes all Network regional Nodes. The study is overseen by the National Coordinating Center.

Study Duration:	12 months
Subject Participation Duration:	Eligible practitioners participating in the qualitative component of the study can be involved in research activities for up-to approximately 3 months. Practitioners participating in the questionnaire component of the study can be involved in research activities for approximately 3 months.
Estimated Time to Complete Enrollment:	Approximately 6 months from the start of the study for the qualitative component and 10 months for the questionnaire study component.

Schematic of CARAD Study Design:

**Phase 1:
Qualitative
Interviews**
T1=Baseline
(6-8 weeks)

- Develop study protocol, CARAD qualitative interview guide, recruitment materials and obtain CIRB approval/local context reviews.
- Recruit a target of 30 practicing dentists, hygienists, or therapists over about 6-8 weeks to participate in a 30-minute structured telephone interview, sample universe of about 500 eligible U.S. dental practitioners enrolled in the Western Node of the National Dental PBRN.



**Phase 1: Analysis
& dissemination**
(T1 + ~4 months)

- Study team transcribes and cleans interview recordings.
- Qualitative data analysis to address Objective 1.
- Disseminate research results through peer-reviewed manuscripts, conference presentations, and other media.



Phase 2: Survey
(T2=T1+~4 months
(~6-8 weeks)

- Conduct CARAD questionnaire with a target of approximately 500 U.S. practitioners enrolled in the Network at the time of launch, over 6-8 weeks.



**Phase 2: Analysis
& dissemination**
(T2 + ~4 months)

- Conduct data cleaning and analyses to address Objective 2.
- Disseminate research results through peer-reviewed manuscripts, conference presentations, and other media.



Closeout

- Prepare study closeout reports and disseminate study findings.

1. KEY ROLES AND CONTACT INFORMATION

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2. INTRODUCTION: BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

2.1. Background Information

As of March 9, 2021, the novel coronavirus SARS-CoV-2 had infected over 29 million people in the United States and caused more than 524,000 deaths from COVID-19 disease. The World Health Organization, U.S. Centers for Disease Control and Prevention (CDC), and state and local governments have issued recommendations for individuals, businesses, schools and other organizations to reduce the spread of the novel coronavirus. For health care providers, including dental practitioners, the CDC, Occupational Safety and Health Administration, American Dental Association, and other organizations developed and routinely update practice guidelines and recommendations. Prevention has had limited success in controlling the spread of the virus. The rapid development and distribution of an effective vaccine will play a crucial role in containing the spread of SARS-CoV-2 in the US. Since the beginning of the pandemic, multiple research teams have been developing and testing SARS-CoV-2 vaccines for safety and effectiveness. Since November 1 2020, there have been three vaccines that have received emergency approval from the Federal Drug Administration (FDA) for use in U.S. adults. The manufacturing effort to produce and distribute vaccines has increased substantially and there are currently over 31 million Americans have been fully vaccinated. However, the presence and spread of new SARS-CoV-2 variants threaten the effectiveness of the existing vaccines and suggest that a long-term and multipronged public health effort will be needed to maintain establish and maintain herd immunity to the coronavirus.

The CARAD 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.(17,18) 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 (19), and change practice patterns of participating dentists.(20,21) Data indicate that enrolled Network practitioners are similar to the general US dental provider population.(22)

2.2 Rationale

Dental providers can play a significant role in delivering COVID-19 (and other) vaccines to the U.S. population, but their participation in this effort remains underexplored. Dental providers are highly skilled at delivering local anesthetics and dealing with needle

anxiety among dental patients, including children, but lack of training and other barriers must be overcome. Prior to the SARS-CoV-2 pandemic, Oregon's scope of practice laws enabled dentists to deliver vaccines of all types, while dentists in Minnesota and Illinois were allowed to provide flu vaccines to patients. In March 2021, the U.S. Department of Health and Human Services amended the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 (23) that enabled dentists and supervised dental students to deliver COVID-19 vaccines. Some states, such as Washington and Oregon, allow supervised dental hygienists to deliver COVID-19 vaccines.

The proposed "Coronavirus Vaccine Acceptability and Readiness Among Dentists (CARAD)" study uses a mixed-methods approach to evaluate dental practitioner's interest and ability to participate in a SARS-COV-2 vaccine delivery program. This study will be conducted with dental practitioners (dentists, dental hygienists, and dental therapists) enrolled in the National Dental Practice-Based Research Network (PBRN). Practitioners with and without vaccine delivery experience will be interviewed. Objective 1 is addressed using qualitative analyses of dentists and hygienists from the Western Region of the Network. Objective 2 is evaluated using survey data from National Dental PBRN general dentists and dental specialists that are typically involved with primary dental care such as pediatric dentists.

2.3 Potential Risks and Benefits

The CARAD study will conduct semi-structured telephone interviews (about 30 minutes in duration) with a target of 30 National Dental PBRN dental practitioners to be recruited by study staff using email and telephone. We will recruit a target of approximately 500 National Dental PBRN dental practitioners to complete a 20-30-minute online questionnaire to assess acceptability and readiness to provide coronavirus vaccines to patients at dental offices. No PHI is collected as part of this survey.

2.3.1 Potential Risks

We will use established data collection quality management procedures developed by the NCC and ARC for recruitment, data collection and security, and results reporting that minimize potential risks. We expect the primary risks to be related to unintended breaches of confidentiality. However, we will work with the NCC and ARC staff to identify, manage, and report incidence of relevant risks. At the conclusion of the study, study data sets will be reviewed and de-identified by the NCC prior to making the data publicly available.

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 interview and 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 will not directly benefit from participation in this study. We expect the broader dissemination of study results to non-study participants, within and outside the Network population, will benefit practitioners and their patients by identifying important factors associated with receiving coronavirus vaccines at or through dental office visits.

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. Analyze the acceptability, appropriateness, and feasibility of adopting COVID-19 and other vaccine delivery programs among dental practitioners with and without existing vaccine program experience, by practice type, setting, and location.</p>	<p>Dental practitioners are well-suited to provide vaccines, but there are substantial supply management and regulatory barriers to overcome, as well as perceived relevance for dental practice.(14)</p>	<p>Qualitative assessment of topic themes identified during practitioner interviews, relating to legal/practice barriers, other feasibility, vaccine hesitancy, and relevance to dental practice.</p>	<p>Up-to 30 interviews are conducted using videoconference technology over 6-8 weeks.</p> <p>Practitioner's Demographic and practice characteristics are obtained from the Network's Practitioner Database</p>

3.2 Secondary

Objectives	Brief Description/Justification of Outcome Measure	Outcome Measured By	Time Frame
<p>Assess levels of acceptability and readiness to participate in alternative COVID-19 vaccine delivery programs, and other vaccine programs, through dental offices, by practitioner and practice characteristics, and accounting for relevant vaccine supply management and legislative factors</p>	<p>Assessing dental practitioners' interest and ability to participate in a large public health effort to vaccinate the U.S. population requires an assessment of salient barriers, ability, and willingness to accept this role.</p>	<p>Outcomes will be assessed using dichotomous categories from 5-point Likert scale responses for: a) level of acceptability of dental providers' role in preventing SARS-CoV-2 transmission through vaccination; b) level of relevance of vaccine delivery for my dental practice; c) level of perceived interest among my dental patients; d) level of confidence for managing vaccine supplies; and e) level of confidence for delivering vaccines at dental office visits. COVID-19, HPV,</p>	<p>Online surveys (and retests) are conducted over about 6-8 weeks.</p> <p>Practitioner's Demographic and practice characteristics are obtained from the Network's Practitioner Database</p>

		and flu vaccine delivery will be assessed. A target of 25-30 test-retests will be conducted to assess item internal validity.	
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4. STUDY DESIGN

The CARAD study uses a mixed-methods approach to evaluate dental practitioners' interest and ability to participate in a COVID-19 vaccine delivery program. This study will be conducted with practitioners enrolled in the National Dental Practice-Based Research Network (PBRN). Objective 1 is addressed using qualitative analyses from telephone interviews with a target of approximately 30 active practitioners enrolled in the Western Region of the network. Objective 2 is evaluated using web-based survey data collected from about 500 active U.S. practitioners across all regions of the network.

We will seek to balance participation between females and males and over-represent racial-ethnic minorities among practitioners from their respective sample populations. The study biostatistician will develop a recruitment sampling frame to group eligible practitioners by gender and race-ethnicity, and other criteria (e.g., practice type, practice setting, practice location) needed to conduct subgroup analyses. An initial and subsequent recruitment sample will be randomly drawn from each population strata and added to a recruitment list. Study staff will maintain and monitor recruitment outcomes using a table of eligible and enrolled practitioners within each stratum, and work with NCC and ARC staff to monitor enrollment rates in each region. We will work with NCC staff to develop weekly recruitment reports to assess enrollment rates by gender, race, and ethnicity, and other strata as defined.

The order of events allows the study team to incorporate salient topics and lessons learned from each preceding activity into subsequent activities. Further, new information learned in the changing landscape of this pandemic will be accounted for with subsequent activities, as appropriate. All recruitment and informed consent processes will be reviewed and approved by the National Dental PBRN Central IRB and regional IRBs where relevant.

5. STUDY POPULATION

The CARAD study includes qualitative and quantitative components. For the qualitative study, a target of 30 active National Dental PBRN practitioners will be enrolled who have a primary practice location residing in the Western Node of the network. For the quantitative (questionnaire) component of the study, a target of approximately 500 active network practitioners will be enrolled. To be eligible, practitioners (dentists, hygienists, therapists) must be enrolled in the National Dental PBRN at Level 2 (limited) or Level 3 (full) participation, an active dentist licensed to practice in the US. The quantitative component involves general dentists and dental specialists that are typically involved with primary dental care such as pediatric dentists and dentists with training in Dental Public Health.

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 at the time of recruitment initiation for the interviews or surveys.
- Is a current limited or full participation member of the National Dental PBRN (Enrollment Questionnaire (EQ) Qx 7).
- Qualitative study: Is a currently a practicing dentist, dental hygienist, or dental therapist in the US (EQ Qx 1: response categories 1-12).
- Quantitative study: Is a currently a practicing dentist in the US (EQ Qx 1: response categories 1-10).
- Dentists identified in the EQ (Q18) as a
 - general dentist
 - a specialist with training in pediatric dentistry or dental public health, as indicated in EQ Q19.
- 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.

- Dental hygienists and dental therapists are excluded from the quantitative study.

Strategies for Recruitment and Retention

Recruitment

Practitioner qualitative interviews. We will recruit a target of approximately 30 active U.S. dental practitioners from the Western Node of the National Dental PBRN to participate. The study team will develop a recruitment table that puts eligible practitioners (using PID numbers) into buckets for gender, race-ethnicity, practice type, practice setting, and practice location. A sampling procedure will be used to select practitioners from each bucket for email or telephone outreach by study staff. Practitioners will be selected from each bucket until the target enrollment sample from each bucket is achieved. Practitioners will be in multiple buckets, so the selection strategy will prioritize selection from underrepresented buckets. Enrolled practitioners will be removed from all other buckets.

Practitioners identified for recruitment will be contacted by study staff using the NCC HUB email system, or by direct study staff email or telephone. Periodic follow-up by NCC or CARAD study staff (using email, telephone, or text) will be conducted over 6-8 weeks until all interviews are completed. Recruitment outreach and outcomes will be maintained by study staff in collaboration with the NCC and Western Node staff as necessary. Interested participants will contact study staff by email or telephone to schedule an interview. Some practitioners may elect to conduct the interview at the time of a recruitment call from a study team member.

Practitioner survey. A target of approximately 500 dentists will be recruited from a sample universe of about 4000 active US dentists in all regional Nodes who are enrolled in the National Dental PBRN (Network) at the time of recruitment and have provided EQ data since June 2019. Eligible participants will be identified from their responses to the network's EQ. The study team will develop a recruitment table that puts eligible practitioners (using PID numbers) into buckets for region, gender, race-ethnicity, practice type, practice setting, and practice location. We seek to enroll a group of dentists that is representative of the network population. Depending on initial recruitment results, a sampling procedure may be used to select practitioners from each bucket for recruitment. Practitioners will be in multiple buckets, so the selection strategy will prioritize selection from underrepresented buckets. Enrolled practitioners will be removed from all other buckets and subsequent recruitment activities. Practitioners will be selected from each bucket until the target enrollment sample from each bucket is achieved.

Network practitioner recruitment will be led by the study team in collaboration with Regional Node staff from the ARC. The network practitioner database managed by the NCC will be used to identify active practitioners who meet the study eligibility criteria. Dentists will be recruited primarily through email containing a brief description of the study and a link to the study questionnaire. Telephone calls and other methods may be used to contact initial non-responders. We will recruit a target of 25-30 responders to

participate in a survey retest within 7-10 days of completing the questionnaire to measure item internal validity.

Participant Incentives

Practitioners participating in the qualitative study will receive \$100 remuneration for their time following completion of the interview. To achieve our recruitment target, we may offer a drawing for participants to receive an item of value equivalent to about \$1500, such as an iPad Pro.

Practitioners will receive \$50 for completing the questionnaire and an additional \$50 for survey retests.

5.3 Participant Withdrawal

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

5.3.1 *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.

5.3.2 *Handling of Participant Withdrawals*

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

It is anticipated that participants will not be replaced.

5.4 Premature Termination or Suspension of Study

This study may be suspended or prematurely terminated if there is sufficient reasonable cause. The PIs are 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 CARAD study is separated into qualitative and questionnaire phases over a 12-months study period. CARAD participants will complete the following activities, in sequential order, at the listed time periods. The information below differentiates between practitioners those participating in qualitative interviews and those participating in the questionnaire.

Activity	Time period
6.1 Phase 1 – Qualitative interviews	
<ul style="list-style-type: none"> Recruit a target of approximately 30 practitioners, review inclusion criteria. Schedule and conduct telephone interviews (~30 minutes in length) over about 6-7 weeks 	12 weeks
<ul style="list-style-type: none"> Transcribe and clean interview data 	10 weeks
<ul style="list-style-type: none"> Conduct analyses and disseminate results 	17 weeks
6.2 Phase 2 – Questionnaire recruitment and conduct	
<ul style="list-style-type: none"> Implement CARAD Questionnaire; obtain responses from about 500 practitioners 	6-8 weeks
<ul style="list-style-type: none"> Conduct data cleaning 	4 weeks
<ul style="list-style-type: none"> Conduct analyses and disseminate results 	8-10 weeks
6.3 Study closeout and results reporting	
<ul style="list-style-type: none"> Complete analyses to address study objectives 	End date

7. STUDY PROCEDURES/EVALUATIONS

Study procedures will follow existing network-approved processes that were developed for previous studies, where available. We will work with the NCC and ARC to develop any new procedures for recruitment, data collection and security, and results reporting that minimize potential risks.

The qualitative interview component of the CARAD study is new to the network, which require new processes for participant recruitment, interview conduct, and data collection, security, and analysis. The survey component of the CARAD study will use existing procedures developed by the NCC and ARC for questionnaire studies.

Qualitative component

Qualitative Interview guide reviews and user testing

The study team conducted informal cognitive testing of the interview guide with members of the Western Node Practitioner Advisory Committee and Practitioner Executive Committee. The study team recruited a Western Node practitioner to conduct a user test of the interview guide, focusing on assessing the length (minutes) and relative importance of proposed topics. Study materials were revised based upon feedback received during and following the cognitive testing process.

Informed consent and documentation

Recruitment outreach will include IRB-approved participant information and elements of informed consent, reviewed electronically or by telephone. All participants will participate in an informed consent process by telephone prior to beginning the interview. The oral consent script will be read by the interviewer. The consent process and participant approval will be recorded, transcribed, and stored in the secure study file service.

Interview conduct

Study staff will conduct telephone interviews with approximately 30 practitioners. The interviews will be recorded and stored in the NCC's secure file system. The recordings will be transcribed for analyses, and identifiers removed. The process will follow standardized procedures developed by the Qualitative Core group at the Center for Health Research.

Questionnaire component

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 User Testing

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

Questionnaire Testing-Retesting

We plan to conduct test-retests of survey questions by survey participants. We will recruit about 25-30 practitioners by email from the initial pool of survey completers

Questionnaire Administration and consent

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 up-to 2 follow-up email reminders, the NCC will provide the Node Coordinators (NCs) with a list of non-responders and partial completers. 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.

Practitioner remuneration

Practitioner remuneration will be managed by the NCC using the newly implemented practitioner payment system.

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 PIs. After the PIs 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 PIs 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 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

The observational CARAD study is exploratory in nature. The study objectives do not include testing specific hypotheses, but rather the research is hypothesis-generating to identify important barriers, facilitators, and other issues guiding dental practitioners' willingness and readiness to provide COVID-19 vaccines (and other vaccines) at dental office visits.

11.2 Final Analysis Plan

Analysis plans. Qualitative and quantitative surveys and analyses will be conducted using practitioner qualitative interview and survey response data.

Practitioner interviews. We will conduct interviews by telephone, and verbal consent will be obtained at the start of the call. An interview guide will be developed based on the Diffusion of Innovations Model (24,25) to assess barriers and facilitators to acceptability, appropriateness, and feasibility of a COVID-19 vaccine delivery program for dental office patients. The Diffusion of Innovations Model proposes that there are several key factors influencing the adoption of innovations in service organizations: characteristics of the adopters (e.g. psychological antecedents and nature of the adoption decisions) and assimilation by the organization, features of the inner context (organizational readiness and antecedents) and outer context (e.g. political directives), influences by opinion leaders.

The interview guide will include questions about experiences with administering the COVID-19 and other vaccines, vaccine delivery workflows in general, perceptions about skills, knowledge and support required to administer the vaccine, and factors that may influence their willingness and interest in administering such a vaccine (including vaccine hesitancy).

Analyses of qualitative data. All recordings will be transcribed by a professional transcriptionist and analyzed using NVivo software. Transcripts will be analyzed following a template analysis. Template analysis is a form of thematic analysis that relies on a formalized coding template. It combines the use of a priori themes (concepts outlined above in the data collection section) with topics that emerge during data review and therefore offers flexibility to capture themes of interest to researchers as well as themes that emerge as relevant to participants during the data collection process. Defining themes both a priori and as they emerge will let us appropriately answer the research question as well as capturing issues that emerge from the interviews.

Analyses of quantitative survey data. We will estimate the mean proportions of practitioners who: a) report the likelihood that their patients are interested/very

perceived to be vaccinated for the coronavirus at a dental office visit; b) report acceptable/very acceptable levels of dental providers' role in preventing SARS-CoV-2 transmission through vaccination; c) report they are confident/very confident in their ability to deliver vaccines at dental office visits; d) report they are confident/very confident their dental practice can manage COVID-19 vaccine supplies with access to adequate temperature control (refrigeration and freezing); and e) report they are willing/very willing to provide COVID-19 vaccines to their patients if known barriers can be overcome. Mean proportions and 95% confidence intervals for each dichotomous outcome will be measured from responses to 5-point Likert scale assessments. We will compare proportions by practitioner type (general dentist, specialists involved with routine care delivery), practice setting (e.g., solo/small group, large group, integrated health system, etc.), practice location, and dentist characteristics. Multivariable logistic regression modeling of outcomes a-e will be conducted if mean proportions differ across multiple factors.

We use the theory of planned behavior (TPB) as a conceptual model for evaluating individual's intentions to perform a given activity as well as actual performance of the activity.²⁵ The TPB posits that behavioral intentions are influenced by the interplay of the individual's attitudes toward the activity, subjective norms, or expectations, to perform the activity, and their perceived level of control over the performing the activity. These factors influence intentions which then predict actual future performance of the activity. Perceived control over the activity also has a direct influence on performance independent of intentions. The TPB has been used to understand medical and dental practitioner's treatment decisions.²⁶⁻²⁹ However, the dental provider's behavior has not been extensively studied.

For this study, **acceptability** is reflected in respondents': a) *personal attitudes* about vaccine safety and effectiveness and receiving vaccinations; b) *professional attitudes* about the roles of the dental profession in general and their individual decisions in particular to promote and deliver vaccines; c) practitioners' perceptions of their patients attitudes about receiving vaccinations; and d) *perceived social norms* reflecting social expectations to provide vaccine recommendations and vaccinations. **Readiness** is reflected in respondents': a) *perceived behavioral control* over vaccine promotion and delivery, including patient demand, regulatory and organizational constraints, supply management and other economic constraints; b) receipt of necessary training; c) *behavioral intentions* to promote and deliver vaccines; and d) having direct experience promoting or delivering vaccines to patients.

Attitudes. We will capture data on practitioners' personal positive and negative attitudes about vaccine safety and effectiveness, and professional attitudes about vaccine advice and delivery to patients. The survey includes 29 questions assessing practitioner attitudes. *Personal perceptions* about vaccinations are captured using 7

questions (the short version) of the 5C model, a validated instrument developed by Betsch and colleagues (2018)³⁰ measures an individual's confidence, constraints, complacency, calculation, and collective responsibility related to receiving vaccinations. We include 13 questions measuring practitioners' professional attitudes about vaccination, and 9 questions adapted 5C questions to measure practitioner beliefs about their patient attitudes about vaccinations.

Subjective norms. We use 12 questions to capture information about practitioners' perceptions of social pressures to recommend and/or provide vaccinations, in general and for COVID-19 disease. We assess perceived pressure from patients, organizations/employers (excluding private practitioners), and professional organizations to recommend or provide vaccinations. We also ask if other local practitioners provide vaccines to their patients.

Perceived behavioral control. We use 25 questions to capture information about practitioners perceived level of control over vaccine recommendations. Control measures include beliefs about their current abilities to provide recommendations and vaccines, comfort providing vaccine counseling, access to training and support, ability to manage supplies, and whether practitioners have sufficient time, patient demand, and compensation. We also assess knowledge about practitioners' state authorization to provide vaccines, ability to explain differences between the mRNA and adenovirus COVID-19 vaccines. We also capture whether changes in these conditions could impact their willingness to provide recommendations and or vaccinations. We assess COVID-19 vaccinations separately from other approved vaccinations.

Practitioner characteristics. We collect practitioner and practice characteristics from the enrollment questionnaire, including age, gender, race, ethnicity, practice type, practice setting, practice region, and state location. We also collect state level COVID-19 policy stringency and case and death rate data for use with the COVID-19-related analyses. We also collect survey data for: a) practice setting; b) rural, suburban, and urban location; and c) whether the practice is located in a healthcare provider shortage area (HPSA).

Behavioral intentions and behavior. *Behavioral intentions* and captured by questions representing practitioners' receipt of training certification to provide vaccines, and their stated willingness to recommend and/or provide vaccines. Vaccine behavior is assessed using self-reported provision of vaccine recommendations or vaccinations for patients. For vaccine delivery, we capture information about providing vaccines through external community organization and/or for their patients at dental offices. We ask separately about vaccinations in general and COVID-19 specifically.

Sample size and power for primary outcome. The design of the qualitative components of the study involve small numbers of patients and practitioners and are developmental in nature. For the quantitative dentist survey (n= about 500), assuming equal group sample size of 100 respondents and a response rate of 0.2 in the reference group, we will be able to detect a difference in proportions of 0.176 (i.e., 0.376 response rate in the comparison group) to achieve 80% power. Alternatively, to detect a difference of 0.2 between the two groups with a response rate of 0.2 in the reference group, we'll need a sample size of 79 dentists per group.

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, PIs 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 source documents for this study are:

- Transcribed interviews from participating practitioners.
- 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.
- Relevant federal, state, and professional society clinical practice guidelines and recommendations for dental provider-delivered COVID-19 and other vaccinations.

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 PIs 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 PIs will submit for IRB approval and provide the Central IRB with the appropriate approved IRB documents.

14.3 Informed Consent Process

The study team will request waivers of documentation of signed informed consent from practitioners who participate in either the qualitative interviews or complete the electronic questionnaire. 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. Study interviewer also will read oral consent script to participants prior to conducting qualitative interviews; verbal consent will be recorded and transcribed. Survey participants also will receive consent information on page one of the Redcap 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 member practitioners 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 PIs will work closely with the NCC to ensure that all electronic data 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 interview transcripts and 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 practitioners for this study.

15.2 Data Capture Methods

Data from the qualitative interviews will be collected via voice recording and transcribed by a professional transcriptionist. The transcriptions will be stored on a secure study file system managed by the NCC.

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 PIs 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 PIs, in accordance with IRB regulations, before being securely erased on agreement by the ARC Director, the NCC Director, and the PIs.

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 PIs will document in study source documents and explain any deviation from the IRB-approved protocol. The PIs 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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