Community Accommodation and Dental Treatment among Patients with Special Needs (CADTAPS)

NIDCR Protocol Number: 21-063-E

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NIDCR Program Official: Dena Fischer, DDS, MSD, MS

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STATEMENT OF COMPLIANCE

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

SIGNATURE PAGE

The signature below constitutes the approval of this protocol and the attachments and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines.

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Signed: _Sydnee Chavis_____ Date: 11/15/2021

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Title:

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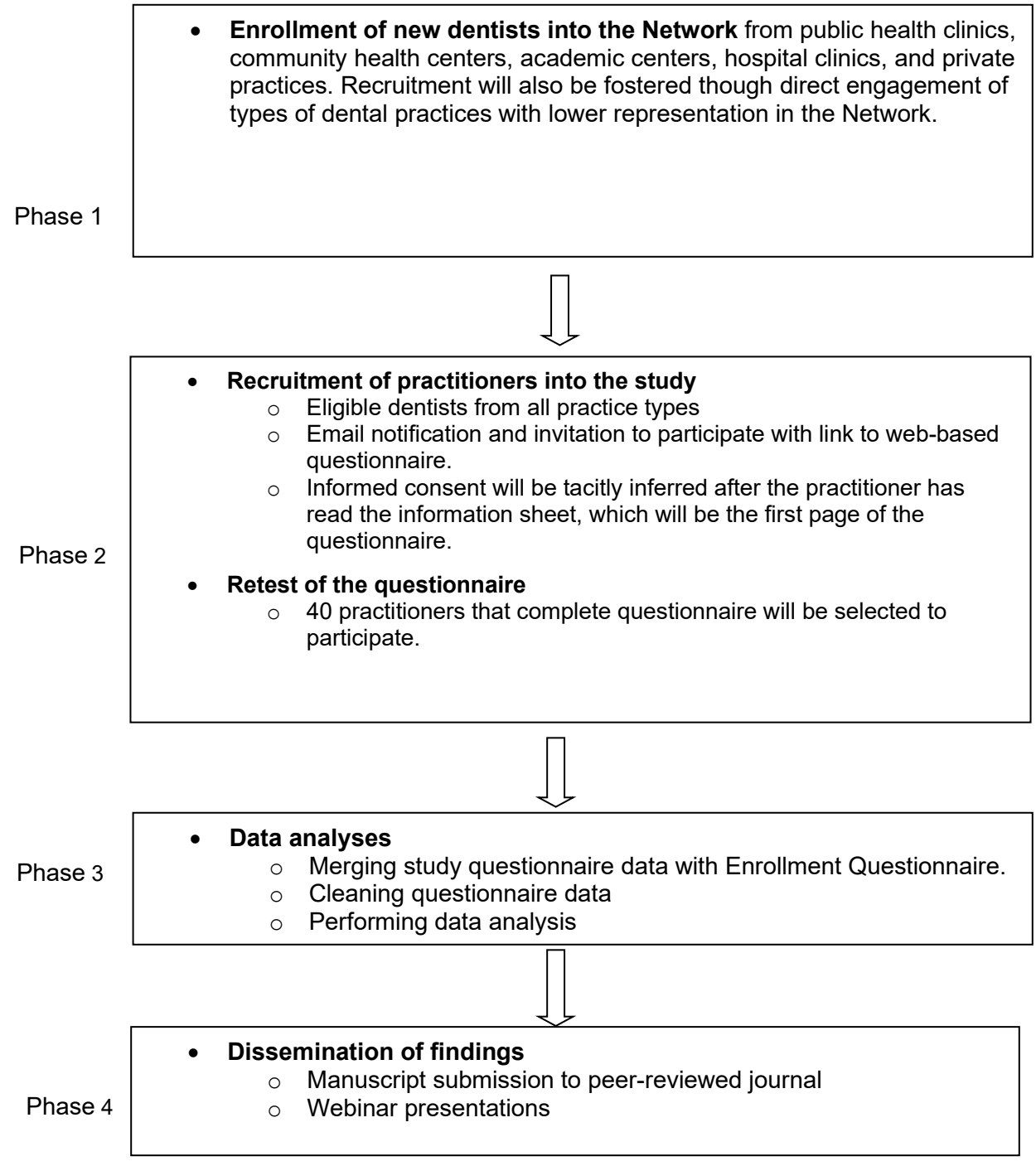
LIST OF ABBREVIATIONS

ADA	American Dental Association
CFR	Code of Federal Regulations
CROMS	Clinical Research Operations and Management Support
EDC	Electronic Data Capture System
DHHS	Department of Health and Human Services
DMP	Data Management Plan
EQ	National Dental PBRN Enrollment Questionnaire
FFR	Federal Financial Report
ICCC	International Caries Consensus Collaboration
ICH	International Council for Harmonisation
IADD	Intellectual, Acquired, and Developmental Disabilities
IRB	Institutional Review Board
Network	National Dental Practice-Based Research Network (DPBRN)
NCC	Network Coordinating Center
NC	Node Coordinator
NIDCR	National Institute of Dental and Craniofacial Research, NIH, DHHS
NIH	National Institutes of Health
OHRP	Office for Human Research Protections
PD	Protocol Deviation
PI	Principal Investigator
PID	Practitioner Identification Number
QA	Quality Assurance
QC	Quality Control
RCT	Randomized Clinical Trial
US	United States

PROTOCOL SUMMARY

Title:	**Community Accommodation and Dental Treatment among Patients with Special Needs (CADTAPS)**
Précis:	This cross-sectional study will investigate the proportion of dentists within the network that treat adults with intellectual, acquired, and developmental disabilities (IADD). The questionnaire will also assess attitudes regarding management of these patients and methods dentists use to treat these patients, as well as reasons dentists may not treat these patients. Dentists from all practice types defined in the National Dental Practice Based Research Network (PBRN) enrollment questionnaire will be surveyed via questionnaire. Responses will be analyzed via descriptive methods as well as logistic regression to assess for differences in proportions of care between practice types.
Objectives and Outcome Measures:	The primary objective is to determine the proportion of participating Network dentists' who provide care for adults with IADD with various behavior tolerances for dental care, both within the network overall and also by practice type, location, and specialty. The secondary objectives are to determine attitudes, perspectives, and rationale for why dentists treat patients with IADD or not, as well as the methods, processes, and procedures participating Network dentists utilize to provide care for adults with IADD. These analyses will be exploratory in nature, and will include a mix of simple descriptive statistics as well as various regression models.
Population:	The study population will include a stratified random sample of approximately 500-550 eligible Network dentists practicing in all practice types.
Number of Sites:	NA
Study Duration:	9 months
Subject Participation Duration:	*One-time completion of online questionnaire (approximately 15 minutes). Approximately 40 participants will complete the online questionnaire a second time for the purposes of establishing test-retest reliability.*
Estimated Time to Complete Enrollment:	3 months

Schematic of Study Design:



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2 INTRODUCTION: BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

2.1 Background Information

The prevalence of autism in the United States is increasing at an astonishing rate, from 1 in 150 in 2000 to 1 in 88 in 2008 to 1 in 59 in 2014.[1] As such, it is becoming one of the most prevalent diagnoses of developmental disability and bringing light to the oral needs of patients with disabilities.[2] The population is aging, and with that comes a higher prevalence of older adults with intellectual, acquired, and developmental disabilities (IADD) such as Down's syndrome, dementia, and autism.[3] Due to increased sensitivity to stimuli it is often particularly difficult for people with autism and other IADD to access and tolerate dental treatment.[4]

It has been widely demonstrated and documented that oral health and dental needs are the most commonly unmet healthcare needs for persons with special healthcare needs, namely IADD.[5,6] People of this population demonstrate worse oral health status and outcomes than the general population, which is both contributed to and amplified by limited behavioral tolerance many of these patients have for dental treatment.[7] As patients continue to age and this population continues to grow, these needs become more amplified and the oral health disparity between persons with IADD and the general population worsens.[8] There are no evidence based methods or best practices for the management of this complex and diverse population. The research also tends to focus on children with special healthcare needs and not adults. While similar extrapolations can be drawn to adult populations as pediatric populations, health disparities between adults with IADD and the general population are more pronounced than those of children.[9]

Furthermore, patients with IADD may be followed by pediatric providers into adulthood.[10] A nationwide study found that only 10% of responding general dentists provide dental care for patients with disabilities.[11] This persistent practice paradigm reduces the capacity for pediatric providers to treat children, but also may impair patient care by the provision of non-age appropriate treatment, as well as longer wait times for treatment to be scheduled and completed in a community based setting that is convenient and accessible for these patients.[12]

This problem of unmet dental and oral health need among this adult population is multifold. Quite a bit of this healthcare disparity stems from difficult access to care for people with IADD.[13,14] Patients with IADD often seek care in the community, but are referred to specialized centers or for general anesthesia or sedation for treatment.[15] This might be due to complex dental needs and diversity of patient population, lack of cooperativity, lack of willingness or ability of a provider to complete the care, or financial barriers, to name a few.[16] Prior studies have demonstrated that the majority of general dentists in the community setting do not feel prepared or confident in their ability to provide dental care for patients with IADD.[17] Respondents in these studies have indicated that they would like additional training in the management of patients with IADD and find additional training desirable. However very little curricular based training exists.[11,18] It has never been specifically studied if dentists in practice settings other

than private practice have similar perspectives regarding their ability or willingness to manage adult patients with IADD.

There is also a gap in the literature regarding methods of improving oral health status and access to dental care for patients with special needs.[19] Whereas there is more research and engagement among medical fields regarding health status of patients with special needs, the dental literature lags.[20] Associations can be drawn from the medical literature to address dental needs, but poor dental and oral health also contributes to poorer medical condition.[21] There are data to suggest that interdisciplinary and interprofessional care help to improve health status for patients with special needs.[22]

2.2 Rationale

This study aims to assess whether and to what extent dentists treat adults with IADD, and to understand whether these patterns of treatment differ by practice type. The information collected will help to further elucidate, on a national level, the proportion of dentists who treat adult patients with IADD in different types of practices. It will also help identify what encourages and facilitates providers to care for adult patients with IADD who have some level of difficulty tolerating dental care, and what discourages and prevents providers from managing and caring for these patients. The results of this study may lead to improvements in access to care and outcomes in the future by addressing identified practice-based limitations and practitioner educational and training deficiencies.

In addition, for practitioners who do treat adult patients with IADD, methods of treatment and management of these patients, including pharmacologic and behavior management methods, referral practices, and the scope of care that they provide will be determined. The questionnaire will be augmented by practice and practitioner-based data available through the National Dental Practice-Based Research Network (PBRN). This will permit a shorter questionnaire while still providing practice and practitioner descriptors useful for identifying characteristics associated with treatment patterns of patients with IADD and behavioral challenges for tolerating dental care.

In short, the study will glean insight regarding who is treating adults with IADD versus referring, how these patients are managed for treatment, how many general dentists versus pediatric dentists versus other specialists are managing these patients, and general attitudes regarding the provision of care for this complex population. There are few studies examining whether general dentists in private practice treat patients with IADD, and there are no studies examining whether dentists in other practice types or specialties provide care for adults with IADD. This questionnaire will guide future research aimed at the development of best practices, as well as curricular, practice based, and continuing education resources for community practitioners regarding the care of patients with IADD with various behavior tolerances for dental care in the clinic setting.

2.3 Potential Risks and Benefits

2.3.1 Potential Risks

This study poses no more than minimal risk to study participants. There are no anticipated physical, psychological, social, legal, economic, or any other anticipated risks to study participants. Study participation is completely voluntary, and participants may discontinue participation at any time without penalty or negative consequences. As with any study, there is the potential for loss of confidentiality; however, appropriate precautions will be taken to mitigate this risk. These precautions include the use of unique study codes for participants and password-protected computers and secure networks for data storage. Compliance with all Institutional Review Board (IRB) regulations concerning data collection, data storage, and data destruction will be strictly observed. Data will only be accessible to research study personnel and will be stored and coded according to OHRP guidelines.

2.3.2 Potential Benefits

There are no direct benefits to the dentists participating in this study; however, this study will contribute to generalizable knowledge concerning the management and treatment of adult patients with IADD. In particular, the data collected will help explore the extent to which dentists are providing care for this population versus referring, and where these patients are ultimately referred to for care. Furthermore, analysis of study results will be used to support the decision regarding whether to proceed with the development of training material and further studies.

3 OBJECTIVES AND OUTCOME MEASURES

3.1 Primary Objective

Objective	Brief Description/Justification of Outcome Measure	Outcome Measured By	Time Frame
The primary objective is to determine the proportion of participating Network dentists who provide care for adults with intellectual, acquired, and developmental disabilities (IADD) with various behavior tolerances for dental care, both within the network overall and also by practice type, location, and specialty.	Dental care for adults with IADD is the most unmet healthcare need, yet prior studies have suggested that very few general dentists treat patients of this population due to lack of confidence, training, and experience. Patients with IADD can have limited behavioral tolerance for dental treatment, and as such they can be more difficult to treat. These patients face significant disparities in oral health care access and outcomes, and understanding dentists' practice patterns could help to elucidate root causes of these disparities. The proportion of dentists who treat adults with IADD has not been studied by specialty and by practice type.	The primary outcome measures will include whether or not dentists provide care for patients with IADD. Level of provision of care will be measured as proportion of providers who affirm they manage adults with IADD/ behavioral difficulties with dental care.	The questionnaire will be conducted over an approximately 3-month period of time.

3.2 Secondary Objective

Objective	Brief Description/Justification of Outcome Measure	Outcome Measured By	Time Frame
The secondary objectives are to determine attitudes, perspectives, and rationale why dentists treat patients with IADD or not, as well as the methods, processes, and procedures	Among providers we want to understand what drives someone to provide care for adults with IADD or not. Among those who do provide care for adults with IADD, there is likely to be a broad spectrum of how providers manage these patients, to what extent they provide direct treatment, and to what extent they refer to more specialized centers. This objective seeks to determine why dentists do or do not treat adults with IADD, and how dentists	The secondary outcome measures will be assessed by proportions for responses regarding methods and practice patterns that dentists implement for adults with IADD. Proportional measures of dentist rationale and methods that they employ with adults with IADD will be	The questionnaire will be conducted over an approximately 3-month period of time.

participating Network dentists utilize to provide care for adults with IADD.	across different practice types, locations, specialties, experience and training levels manage and treat adults with IADD.	reported across respondent practice types and specialties.	

4 STUDY DESIGN

This study is a cross-sectional questionnaire of Network dentists practicing all practice types that are represented in the Network. Responses to the questionnaire will be analyzed by the type of practice setting of the respondent.

Recruitment will be stratified by practice setting, with the goal of obtaining approximately equal numbers of providers from (1) all private practices via random sample and (2) all other practice types of whom all will be invited to participate, with a total respondent sample size of approximately 500-550.

Eligible Network dentists as described in the previous paragraph will be sent an email invitation to participate in the questionnaire study. The questionnaire will take approximately 15 minutes to complete and will be administered using the Electronic Data Capture System (EDC) on the Network HUB website, housed at the Network Coordinating Center (NCC).

Following the launch of the questionnaire, approximately 40 of the initial survey responders will be selected to complete the electronic questionnaire again (approximately 2 weeks post initial questionnaire completion) to establish test-retest reliability.

Approximately 3 months are estimated to complete recruitment into the study to obtain the desired sample size.

5 STUDY POPULATION

5.1 Participant Inclusion Criteria

To be eligible to participate in this study, an individual must meet all of the following criteria:

- Is a current limited or full participation member of the Network (EQ Qx 7 ParticipationLevel);
- Is a practicing dentist in the US (EQ Qx 1 PrimaryOccupation: response categories 1-10);
- Has verified EQ contact information on file since 01-2020 at which he or she can be contacted (EQ contact information);
- Indicates that no more than 80% of their patient population is 18 or less (EQ Qx 11 PercentAgeChildren)
- Indicates they personally provide direct patient care for at least 1 adult patient visit in a typical work week (EQ Qx 22 PatientVisitsPerWeek)

5.2 Strategies for Recruitment and Retention

Recruitment

As of September 2021, 7,748 members were enrolled in the National Dental PBRN. Of this total, approximately 34% are dentists providing care in private practices of any size, including managed care organizations, and approximately 8% are dentists providing care in community health centers, academic dental centers, hospitals, corporate offices, and other practice types. We will actively recruit new dentists from public health clinics, community health centers and academic dental centers to join the Network via, as practitioners within these practice types are underrepresented in the Network, as well as are more likely to treat patients with IADD.

Dentists will be recruited from the following two strata: private practices dentists; and all other Network dentists. Sampling fractions will be determined based on the number of dentists in these two strata at the time of recruitment, with the goal of obtaining roughly equal numbers of dentists in each stratum if possible. Based on current numbers and assuming a response rate of 50%, we anticipate contacting approximately 20% of private practice dentists and 100% of other dentists, with projected enrollment for the two strata of approximately equal numbers participants per each group.

Dentists will be contacted via e-mail with a link to a web-based questionnaire. Those who do not respond will be sent e-mail reminders once a week for two weeks following initial contact. If no response after the two e-mail reminders, National Dental PBRN

Node Coordinators (NCs) will engage in recruitment, contacting individuals who have not completed the questionnaire. Meetings will be held as needed with Regional NCs to review recruitment issues and enrollment progress. NCs will prioritize follow up with non-private practice practitioners to promote equal sampling from each practice type to maximize the generalizability of the sample, recruitment efforts may continue beyond a sample of approximately 500-550 respondents.

Compensation

Participants who wish to receive compensation and are able to accept payment will be remunerated $50 for completing the electronic questionnaire. If participants complete the test-retest of the electronic questionnaire, they will be remunerated an additional $50. Payment will be sent to participants following the conclusion of each of the waves of the study.

5.3 Participant Withdrawal

5.3.1 Reasons for Participant Withdrawal

Participants can choose not to participate in the study and are free to withdraw, i.e., not complete the questionnaire, at any time without penalty.

5.3.2 Handling of Participant Withdrawals

We anticipate only a single recruitment mailing. Individuals who complete only part of the questionnaire may be included in some analyses depending upon the completeness of their data.

5.4 Premature Termination or Suspension of Study

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

6.1 Phase 1 – Enrollment of New Practitioners into the Network

- Dentists practicing in all practice types will be encouraged to enroll into the Network. Recruitment will draw from practice types that and underrepresented in the Network, such as hospital and academic settings, that may also focus of the provision of dental care for patients with IADD.

- Dentists in these practice settings tend to treat patients with a higher prevalence and incidence of patients with IADD and are therefore suited to answer the study questionnaire regarding treatment strategies and methods for patients with IADD.

6.2 Phase 2, Part A – Recruitment of Practitioners into the Study

Eligible dentists will be identified from responses to the Network Enrollment Questionnaire and will be invited to participate based on inclusion criteria.

A random sample of eligible dentists in the Network from the private practices will be taken, and all dentists from other practice types will be invited to participate.

Agreement to complete the questionnaire will indicate that study participants have read the consent information, and this will imply tacit consent. A waiver of signed consent will be requested from the IRB.

Phase 2, Part B– Retest of the Questionnaire

Dentists selected from among those study participants who completed the questionnaire will be emailed a second online questionnaire request approximately two weeks after the receipt of their first completed questionnaire.

Dentists will be informed they have approximately one week to respond to the invitation to complete the retest. If the retest is not completed within the approximate one-week time frame, the link to the retest questionnaire will be disabled. A new potential retest participant will be selected from those having already completed the questionnaire until a total of approximately 40 retests have been completed.

Completion of the retest questionnaire will indicate implied consent.

Phase 3 – Merging Study Questionnaire with Enrollment Questionnaire and Completion of Data Analyses

Study questionnaire and Network enrollment questionnaire data will be linked using participant IDs.

Contact information will be removed from the final merged dataset and data will be stored/saved using Unique Participant IDs.

Data Analyses will be completed as described in Section 11.3 Final Analysis Plan.

7 STUDY PROCEDURES/EVALUATIONS

Questionnaire Development

The study questionnaire was developed by the study team. The questionnaire has undergone review by the NCC to ensure it is psychometrically sound and to ensure the data it collects will allow for adequate evaluation of study objectives. Further, cognitive testing of the questionnaire 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 accurately.

Questionnaire User Testing

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

Questionnaire Administration

According to the inclusion criteria, eligible participants, i.e., Network dentists whose practice includes the full scope of dental procedures will be identified from their responses to the Network's enrollment questionnaire.

Consistent with regulations outlined by the University of Alabama IRB and regional/local IRBs, information about the study will be provided to all eligible participants via an information sheet/questionnaire link in the email invitation.

After the initial invitation and follow-up email reminders, the NCs will systematically contact non-responders, and participants with incomplete information, by email, phone, or fax to encourage questionnaire completion. If no feedback is received or the participant does not complete the questionnaire after these follow-up attempts, it will be assumed the practitioner is not interested in the study. NCs may also contact participants as part of data cleaning conducted by the NCC.

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 Network 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 outlined in the Data Management Plan. 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 a cross-sectional questionnaire of Network dentists assessing their treatment practices regarding the management of adults with IADD. The primary objective will test the hypothesis that a lower proportion of dentists in private practice treat patients with IADD than dentists in other practice types. The secondary objective will provide descriptive data. As such, formal hypothesis testing will not be conducted to achieve the secondary objectives.

11.2 Sample Size Considerations

11.1 Considerations

The primary objective of the study is descriptive (i.e., to understand the proportion of dentists in different practice types that treat adults with IADD). As such, sample size calculations are based on the precision with which we can estimate confidence interval widths. To a good approximation, if W is the width of the 95% confidence interval (i.e., the confidence interval is of the form P ± W/2) for an estimated proportion P based on a simple random sample of N observations, then the N needed to achieve that width is given by

$$N \cong 16*P*(1-P) / (W^2),$$

where P and W are expressed on a fractional basis. Thus, a proportion of 20% corresponds to P=0.20, and if the width of the confidence interval were 10 percentage points, then W would be 0.10. For a given value of W, the formula above is symmetric about P=0.5 and is largest for P=0.5. Hence using P=0.5 above will give a conservative value of N that assures a width ≤ W regardless of the value of P.

Similarly, the above formula can be used to solve for the precision of a CI given the sample size. In this case we get

$$W \cong 4*SQRT\{P*(1-P) /N\}.$$

For the overall population estimate, or indeed any estimate not restricted to one of the two practice strata used for sampling, the above formulas will be biased in that they do not account for the impact of variability introduced by the sampling. Nonetheless they should serve as a good ballpark estimates. For those estimates that are limited to one of the practice strata used for sampling, the above formulas should be unbiased.

Table 1 shows the precision (in this case expressed as W/2, or the half-width of a 95% confidence interval) for various combinations of N and P. Thus, the

corresponding intervals would be of the form P ± W/2. Since the results will be symmetric about P=0.5, we only present results for P ≤ 0.5. The calculations for N=500 correspond to prevalence estimates for the sample as a whole, and as noted above may be somewhat inaccurate since they do not account for the stratified sampling. The other calculations reflect potential sample sizes for the various practice types and are not affected by the sampling. We assume these subgroup sample sizes may vary anywhere from 50 to 150. To interpret the table, consider an N of 100 and a prevalence of 0.4. Per the table, we would estimate the true proportion with 95% CI P ± .096. In the worst case shown in the table (group size of 50 and a prevalence of .5), the 95% CI would be of the form P ± .139.

Table 1. Size of half width of 95% CI for simple proportion.

	N				
true prevalence	**50**	**75**	**100**	**150**	**500**
0.10	0.083	0.068	0.059	0.048	0.026
0.15	0.099	0.081	0.070	0.057	0.031
0.20	0.111	0.091	0.078	0.064	0.035
0.25	0.120	0.098	0.085	0.069	0.038
0.30	0.127	0.104	0.090	0.073	0.040
0.35	0.132	0.108	0.093	0.076	0.042
0.40	0.136	0.111	0.096	0.078	0.043
0.45	0.138	0.113	0.098	0.080	0.044
0.50	0.139	0.113	0.098	0.080	0.044

calculations assume simple random sampling

11.2 Final Analysis Plan

Primary Objective: The primary objective is to determine the proportion of participating Network dentists' who provide care for adults with IADD with various behavior tolerances for dental care, both within the network overall and also by practice type, location, and specialty. All calculations will adjust for the stratified nature of the sampling in order to provide unbiased estimates and accurate confidence intervals. For both the population as a whole and the various subgroups of interest, we will calculate both estimated prevalences and their corresponding 95% confidence intervals. Secondary analyses will use logistic regression models to assess factors that are associated with the treatment of these patients.

Secondary Objective: Additional secondary outcomes are to determine attitudes, perspectives, and rationale why dentists treat patients with IADD or not, as well as the methods, processes, and procedures participating Network dentists utilize to provide care for adults with IADD. These analyses will be exploratory in nature, and will include a mix of simple descriptive statistics as well as various regression models.

Additionally, these data will be evaluated to determine the feasibility of the development of a training protocol for methods or procedures to encourage dentists to manage and treat adults with IADD more broadly.

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 questionnaire into their EDC. 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 source documents for this study are:

- Electronic study questionnaire administered through the NCC EDC on the HUB website.
- Data collected in the Network Enrollment Questionnaire.

13 QUALITY CONTROL AND QUALITY ASSURANCE

For the Quality Control (QC) and Quality Assurance (QA) activities associated with data collection and processing, the NCC will develop a Data Management Plan in which the specific data QC/QA procedures will be provided. These procedures will include the development of 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 Network's Central Institutional Review Board (IRB) for review and approval. The UAB IRB for Human Use serves as the Network's 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

The standard waiver of documentation of signed informed consent for internet-based surveys will be requested for this study. Consistent with regulations outlined by the Central IRB, informed consent language will be provided on the entry page to the questionnaire and will indicate that consent is provided if the respondent chooses to enter the questionnaire via the link they have been provided (tacit consent).

14.4 Exclusion of Women, Minorities, and Specific Age Groups

Network 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 Network) 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.

The National Program Manager, who will be responsible for ensuring Network dentists completing the questionnaire are remunerated $50, will be provided the minimum information necessary from the questionnaire to fulfill the responsibility of appropriately directing practitioner payments to their desired address.

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 as outlined in the DMP. 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 completely, 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. The DMP will include details on the EDC 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 approximately monthly, or more frequently if desired, 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 PI 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 PI will document in study source documents and explain any deviation from the IRB-approved protocol. The PI will report to the IRB any deviations or changes made to eliminate immediate hazards to participants and any changes that increase risk to participants and/or significantly affect the conduct of the study.

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

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/.

17 LITERATURE REFERENCES

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