

Substance Use Disorders Screening (SUDS)

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STATEMENT OF COMPLIANCE

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

SIGNATURE PAGE

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

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LIST OF ABBREVIATIONS

AAP	American Academy of Pediatrics
ADA	American Dental Association
ARC	Administrative Resource Core
AUDIT	Alcohol Use Disorders Identification Test
BSTAD	Brief Screener for Alcohol Tobacco and Other Drugs
CARET	Comorbidity Alcohol Risk Evaluation Tool
CFR	Code of Federal Regulations
CoC	Certificate of Confidentiality
CROMS	Clinical Research Operations and Management Support
DAST	Drug Abuse Screening Test
DM	Data Manager
EDC	Electronic Data Capture System
G-MAST	Geriatric Michigan Alcoholism Screening Test
HHS	Department of Health and Human Services
DMP	Data Management Plan
FFR	Federal Financial Report
ICH	International Council for Harmonisation
IRB	Institutional Review Board
MUSC	Medical University of South Carolina
Network	National Dental Practice-Based Research Network (DPBRN)
NC	Node Coordinator
NCC	Network Coordinating Center
NIDCR	National Institute of Dental and Craniofacial Research, NIH, DHHS
NIH	National Institutes of Health
OHRP	Office for Human Research Protections
ORT	Opioid Risk Tool
PD	Protocol Deviation
PEC	Practitioner Executive Committee
(S) PI	(Site) Principal Investigator
PID	Practitioner Identification Number
QA	Quality Assurance
QC	Quality Control

S2BI	Screening to Brief Intervention
SUD	Substance Use Disorder
TAPS	Tobacco, Alcohol, Prescription medication, and other Substance Use
UAB	University of Alabama Birmingham
US	United States
USPSTF	United States Preventive Services Taskforce

PROTOCOL SUMMARY

- Title:** Substance Use Disorders Screening (SUDS)
- Précis:** This study aims to identify critical training and implementation gaps in performing substance use (including tobacco/nicotine, alcohol, prescription misuse, and illicit drugs) screening among adolescent, young adult, and adult patients in dental offices/practices. This study consists of an online survey of member dentists regarding their current knowledge, training experiences, and practice behaviors related to substance use screening of patients. Data from the survey will be paired with key practice-related enrollment data to identify implementation gaps and whether these gaps vary by practice/practitioner characteristics, as well as to inform the development of training and interventions targeting enhanced substance use screening and early intervention in dental practices.
- Objectives and Outcome Measures:** The primary objective of this study is to conduct a national survey of dentists to assess knowledge, attitudes, and current behaviors related to substance use screening implementation among adolescent, young adult, and adult dental patients.
- The secondary objectives are to identify practitioner- and practice-level facilitators and barriers of: (1) substance use screening implementation; and (2) early intervention and/or referral strategies for patients when indicated.
- Outcome measures will be assessed by an electronic questionnaire regarding current clinical practice and perspectives regarding screening for problematic substance use among patients from adolescence to older adulthood. All data will be self-reported by consenting, participating dentists.
- Population:** The study population will include a random sample of dentists, stratified to ensure representation across participating regions in the US. A census of eligible Network dentists at Level 2 (limited) or Level 3 (full) participation who are actively practicing across the US regions will be invited to participate. The target sample size is 825. Pediatric dentists will be oversampled to ensure that a minimum of 50 pediatric dentists participate.
- Number of Sites:** NA
- Study Duration:** 15 months

Subject Participation Duration: One-time completion of online questionnaire (no more than 30 minutes; \$50 remuneration). Approximately 50 participants will complete the online questionnaire a second time for the purposes of establishing test-retest reliability.

Estimated Time to Complete Enrollment: Approximately 3 months

Schematic of Study Design:

Phase 1

- Summarize the State of the Science for protocol rationale and presentation to the PEC/Ad-hoc advisory board
- Draft methodologic framework for the study protocol, including sample size, recruitment, and sampling methods



Phase 2

- **Develop the Survey/Questionnaire**
 - Form ad-hoc advisory board constituted by PEC members and experts in the areas of assessment of substance use disorders
 - Elicit feedback/develop consensus regarding topics, item types, and key questions (to inform analysis plan) for survey development
 - Develop full draft of survey for Advisory Board edits/feedback
 - Integrate Advisory Board feedback and integrate psychometric feedback from NCC
- **Finalize Questionnaire & Protocol**
 - Finalize survey, protocol, regulatory documents, recruitment materials and attain necessary approvals



Phase 3

- **Recruit Participants (825 Dentists) to Complete Questionnaire**
 - Email notification and invitation to participate with link to web-based questionnaire
 - Informed consent will be tacitly inferred after the practitioner has read the information sheet, which will be the first page of the questionnaire



Phase 4

- **Data Analysis and Dissemination of Findings**
 - Merging study questionnaire data with Enrollment Questionnaire
 - Manuscript submission to peer-reviewed journal
 - Webinar presentation

1 KEY ROLES AND CONTACT INFORMATION

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2 INTRODUCTION: BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

2.1 Background Information

Scope & Impact of Substance Use Disorders in the United States

The United States (US) drug overdose death rate hit its highest level on record in 2021, accounting for the loss of nearly 108,000 American lives.¹ Opioids, particularly synthetic opioids like fentanyl, remain the key contributor to escalating overdose rates, and are involved in more than 80% of all overdose deaths.² Of note, the country is also experiencing tragic increases in overdose deaths that implicate cocaine use, psychostimulants (i.e., methamphetamine and ecstasy), and polysubstance use.^{3,4}

While the finality of overdose deaths warrants the current attention as a critical target of intervention, the impact of problematic substance use extends well beyond mortality rates. Substance use disorders (SUDs) are common, with previous general population studies estimating a prevalence between 8 and 10% among individuals 12 years of age or older.^{5,6} Taken together, the current estimated economic cost of SUDs in the United States is approximated at \$3.73 trillion annually – consisting of \$50 billion in tangible costs (i.e., health expenditures, loss of productivity, criminal justice, accidents, public assistance programming, and research and prevention efforts), as well as \$3.23 trillion in the intangible costs of quality life years lost.⁷ In 2020, more than 5 million Americans reported current cocaine use, 2.5 million Americans reported current methamphetamine use, between 6 and 7 million Americans were estimated to have an opioid use disorder, and around 4 million Americans reported having a marijuana use disorder.⁸

Alcohol use disorders are the most prevalent of all SUDs worldwide, with data from the National Epidemiologic Survey on Alcohol and Related Conditions indicating that 14% of adults aged 18 years or older met criteria for current alcohol use disorder and a staggering 29% had met criteria for an alcohol use disorder in their lifetime.^{9,10} More broadly, nearly 30% of American adults use alcohol in a problematic or unhealthy manner (e.g., exceeding National Institute on Alcohol Abuse and Alcoholism daily or weekly limits).¹¹ Similarly, tobacco use is widely prevalent and remains a leading preventable cause of mortality, responsible for more than 480,000 deaths per year.^{12,13}

A range of evidence-based treatments exist for SUDs, particularly for alcohol, tobacco, and opioid use disorders, often involving psychosocial and pharmacologic interventions either in combination or isolation.¹⁴⁻¹⁸ Unfortunately, these treatments go vastly underutilized.¹⁹ Though economic estimates that approximately 20% of healthcare costs are spent treating conditions and complications associated with SUDs, only around 1% of healthcare dollars are spent treating SUDs themselves.²⁰ Individuals with SUDs are also notably over-represented in healthcare settings, with SUDs prevalence ranging from 15-20% in primary care clinics, around 40% in hospital clinics, and over 70% in emergency/urgent care facilities.^{21,22}

Recommendations for Screening for SUDs in Medical Settings

Given the prevalence and dire health consequences associated with SUDs, the United States Preventive Services Task Force has recommended that all adults be screened for unhealthy use of alcohol, tobacco, and other drugs in primary care settings.²³⁻²⁵ Of note, unhealthy use of alcohol, tobacco, or other drugs may also be identified via methods other than direct screening, including from spontaneous patient report, physical examination, laboratory testing such as a

urine drug screen or blood toxicology report, or as a factor involved in a patient accident/injury. However, in this context, screening for problematic substance use behavior involves asking questions regarding unhealthy use of alcohol, nicotine, and illegal drugs, as well as misuse of prescribed medications, either verbally or in writing (e.g., health history form). A summary of evidence-based and/or screening tests/forms recommended for use in healthcare settings is presented below in *Table 1*.

*Table 1. Recommended screening instruments.*²⁶⁻³⁹

Tool	Substance		Patient Age		Administration	Type
	Alcohol	Drugs	Adults	Teens		
Tobacco, Alcohol, Prescription medication, and other Substance use (TAPS)*	X	X	X		Self/Clinician	Screen/Assessment
Brief Screener for Alcohol, Tobacco, and other Drugs (BSTAD)*	X	X		X	Self/Clinician	Screen
Screening to Brief Intervention (S2BI)*	X	X		X	Self/Clinician	Screen
Opioid Risk Tool (ORT)*		X	X		Self	Screen
CRAFFT*	X	X		X	Self/Clinician	Assessment
Drug Abuse Screen Test (DAST-10)		X	X		Self/Clinician	Assessment
Drug Abuse Screen Test – Adolescent (DAST-A)		X		X	Self/Clinician	Assessment
Single-Question Screening		X	X		Clinician	Screen
Single-Item Screening	X		X		Clinician	Screen
Alcohol Use Disorders Identification Test (AUDIT-C)	X		X		Self/Clinician	Screen
Alcohol Use Disorders Identification Test (AUDIT)	X		X		Self/Clinician	Assessment
CAGE	X		X		Clinician	Assessment
Geriatric Michigan Alcoholism Screening Test (G-MAST)	X		X [#]		Clinician	Assessment
The Comorbidity Alcohol Risk Evaluation Tool (CARET)	X		X [#]		Clinician	Assessment

* Recommended as evidence-based screening or assessment tool by National Institute on Drug Abuse. ++ Screening instruments consist of less than 5 items; Assessments are intended for use when indicated by screening and assess extent of substance use behavior/use disorders in more detail. # Indicated for use with older adults/geriatric populations to assess problems associated with alcohol use.

Beyond SUD screening implementation, evidence from clinical trial data supports the USPSTF recommendation that primary care settings provide a brief counseling intervention and – when appropriate – a referral to formal treatment - to all adults in primary care who screen positive for unhealthy alcohol use.⁴⁰⁻⁴² Brief intervention focuses on increasing insight and awareness regarding substance use behaviors and increasing motivation to decrease harmful use, whereas referral to treatment facilitates connection to more extensive treatment, usually in the context of a specialty care provider.⁴³ Similarly, smoking prevention counseling following the “Five A’s” (ask, advise, assess, assist, and arrange) has been recommended for implementation with adolescents and adults in primary care settings.⁴⁴⁻⁴⁶ Of note, the USPSTF panel has not currently found

sufficient evidence to recommend universal brief intervention in primary care settings for: adolescents identified with unhealthy alcohol use, adolescents or adults identified with other drug use, or adolescents or adults identified with alcohol or drug use disorders.²³ Additionally, less consistently meaningful effects have been found for brief interventions implemented in healthcare settings beyond primary care (e.g., inpatient care, emergency departments, mental health treatment, and surgical).⁴⁹

Ample evidence suggests that use of brief screening questionnaires is feasible; however, general implementation rates in frontline healthcare settings like primary care are largely disappointing.⁵⁰⁻⁵³ Further, recent data from administrative commercial and Medicaid healthcare plans indicates that increases in identification of substance use disorders has not been associated with commensurate increases in these individuals' connection with treatment.⁵⁴ To address the discrepancy between identification of SUD and connection with SUD treatment, efforts have increased to integrate addiction pharmacotherapy and/or behavioral interventions into diverse healthcare settings, including point of care naloxone distribution, nicotine replacement therapy sampling, and initiation of medication for opioid use disorder treatment.⁵⁵⁻⁵⁸

Special Considerations in Screening Adolescents for Risky Substance Use

Substance use is common among US adolescents, with about 27% and 31% endorsing lifetime use of any illicit drug or alcohol, respectively.⁵⁹ Of note, any level of use of alcohol, tobacco, or other drugs among adolescents is viewed as potentially problematic and potentially triggering brief intervention or referral given developmental considerations and heightened concerns for associated harms and continued substance use trajectories resulting in adult SUD.⁶⁰⁻⁶⁴ As with adults, adolescent substance use are of relevance to dentists given their prevalence and association with oral health.⁶⁵⁻⁶⁹

Though the USPSTF found insufficient evidence to assess the harm/benefit balance for screening and brief behavior counseling for unhealthy alcohol and drug use among adolescents, the American Academy of Pediatrics (AAP)/Bright Futures guidelines recommend annual screening for tobacco, alcohol, and other substance use starting at 11 years of age.^{23,24,70-78} Clinicians are further encouraged to begin discussions regarding the harms associated with drinking alcohol earlier, around 9 years of age.^{79,80} Guidelines recommend directly asking the adolescent about their experiences with/use of tobacco, alcohol, or drugs, making specific efforts to include smokeless tobacco, e-cigarettes/vaping, inhalants, cannabis, steroids, and nonmedical use of prescription drugs in these queries.^{59,73,80} If use is indicated, additional questions regarding duration, frequency and amount of use should follow. For screening for problematic substance use, the AAP recommends use of the CRAFFT screen (see *Table 1*).²⁷

Rationale for SUD Screening in Dental Practices

Dental practices represent a largely untapped resource for the identification and early intervention regarding problematic substance use behaviors. Many dental practitioners establish long-term patient relationships that provide frequent opportunities for screening and intervention.^{81,82} Dentists regularly provide care to patients who may not present in other healthcare settings, as well as patients who endorse misuse and abuse of substances.⁸³⁻⁸⁵ Further, knowledge regarding patient substance use is particularly relevant to dental practitioners given impacts that substance use disorders (e.g., methamphetamine use, alcohol use, tobacco use) and their associated behavioral comorbidities may have on oral health,⁸⁶⁻⁸⁹ as well as the frequency with which dentists prescribe

medications that are commonly abused or interact with substances of abuse (i.e., opioids and antibiotics).⁹⁰⁻⁹³ As such the American Dental Association (ADA)⁹⁴ recently released a “Statement on Provision of Dental Treatment for Patients with Substance Use Disorders,” which encourages the following:

- Awareness of each patient’s substance use history that is taken into consideration when planning treatment and prescribing medications
- Knowledge about substance use disorders – active and in remission – to safely prescribe controlled substances and other medications to patients with these disorders
- Professional judgment in advising patients who are heavy drinkers to cut back, or users of illegal drugs to stop
- Seeking consultation with the patient’s physician when the patient has a history of alcoholism or other substance use disorder
- Staying up to date in knowledge regarding pharmacology, including content related to drugs of abuse; recognition of contraindications to the delivery of epinephrine containing anesthetics; safe prescribing practices for patients with substance use disorders; and management of emergencies that may result from unforeseen drug interactions.
- Protect patient confidentiality of substance abuse treatment information in accordance with applicable state and federal law

Implementation of SUD Screening in Dental Practices

In recognition of the prevalence and impact of problematic substance use among dental patients, recommendations for screening and intervention among adult and adolescent patients in the dental setting have been presented in various peer-reviewed outlets.⁹⁵⁻⁹⁹ Recommendations generally follow those issued for other frontline healthcare settings (e.g., primary care) and involve selection of brief, evidence-based screeners paired with more in-depth assessment of problematic use when indicated. Recommendations encourage universal screening of patients, starting with early discussions around harms associated with substance misuse among elementary-aged (9 and older) patients that transition to include screening around age 11-12 years.

Several previous studies have directly assessed dentists’ implementation of screening for various forms of problematic substance use. McNeely¹⁰⁰ and colleagues surveyed dentist members of the former PEARL dental network (N=143; 68% response rate) regarding their attitudes and practice behaviors – including barriers to implementation - related to screening, counseling, and offering referrals to individuals with problematic use of alcohol, tobacco, and illicit drugs (narcotics, illegal drugs, and nonmedical use of prescription drugs). Almost all dentists reported viewing screening for problematic tobacco, alcohol, and illicit drug use somewhat or very important. Most dentists reported including screening for tobacco (93%), alcohol (76%), and illicit drug use (73%) as part of their medical history form. Most dentists also reported asking patients about their tobacco use orally (78%), though less than half reported orally assessing alcohol (44%) or illicit drug use (33%) with patients. More than half of dentists reported providing brief counseling or referrals when indicated for tobacco use (63%); however, fewer than one-third of dentists reported doing so when indicated for alcohol use (29%) or illicit drug use (25%). Key barriers to implementation identified by dentists included lack of training/knowledge (particularly with respect to alcohol and illicit drug use), followed by lack of referrals, and perceived/anticipated staff resistance. Nearly a third of dentists also identified lack of time and perceived ineffectiveness as barriers to addressing alcohol and illicit drug use.

Subsequently, Parish and colleagues¹⁰¹ conducted a nationally representative (n=1802; 71% response rate) survey of US dentists using a sampling frame from the ADA Survey Center assessing the relationship between their practice, knowledge, behaviors, and attitudes with their query about substance misuse and their belief that such screening is part of their professional role. Approximately three-quarters of dentists reported asking their patients about substance misuse on their patient health history form; however, approximately two-thirds did not agree that such screening was compatible with their professional role. More than one-third of respondents had no prior training in substance misuse and self-reported clinical knowledge regarding illicit drug use was low, with more than 20% endorsing “none/limited” knowledge in this area. Prior training regarding substance misuse was positively associated with dentists’ viewing such screening as compatible with their professional role.

McCauley and colleagues¹⁰²⁻¹⁰⁴ surveyed practicing dentist members of the National Dental Practice Based Research Network (Network; N=822; 58% response rate) regarding pain management prescribing practices and risk mitigation implementation, including implementation of screening for substance use broadly. Most dentists reported including assessment of current tobacco use (94%), current alcohol use (75%), and current illicit drug use (69%). However, only slightly more than half (52%) reported assessing patients for current prescription drug abuse and/or history of substance abuse treatment.¹⁰² Further, nearly half of respondents reported having never accessed their state prescription drug monitoring program.¹⁰³ Higher frequency of assessing for substance misuse and abuse was associated with more conservative opioid prescribing practices.¹⁰² Training related to identification and assessment of drug abuse/addiction (48%) or identification of prescription drug diversion (25%) was uncommon, though more prevalent among recent dental school graduates. Training experiences were associated with prescribing practices including greater frequency of providing patient education and higher frequency of drug monitoring program use.¹⁰⁴

More recently, Staras and colleagues¹⁰⁵ surveyed active dentist and hygienist members (N=475, 72% response rate) of the South Atlantic Region of the Network regarding their health risk assessment practices (including screening, measuring, discussing, referring patients) for 6 health conditions including alcohol use and tobacco use. Results indicated that nearly three-quarters of respondents reported “at least occasionally” completing 1 or more of the health risk assessment steps for both alcohol and tobacco use. A key barrier identified by this study was practitioner discomfort, which was particularly relevant to alcohol use health risk assessment. Further, each 10% increase in the proportion of practice patients 18 years or younger in age was associated with a 20% decrease in the likelihood of completing each additional step of the health risk assessment for tobacco use.

2.2 Rationale for Current Study

Existing literature indicates that although dentists regularly encounter patients with problematic substance use and recognize the importance of screening for substance abuse, they have limited exposure to addictions training and generally lack systems to aid in screening, intervention, and referral to addictions treatment and often under-representing patients’ substance use in their medical records.¹⁰⁶ However, several critical gaps exist in our foundational knowledge regarding dentists’ implementation of SUD screening. First, most prior work in this area has focused on implementation of tobacco, alcohol, and – more recently – opioid screening, with very little work addressing dentists’ implementation of screening for other substances of abuse, particularly cannabis and stimulants. Second, except for recent studies specific to opioid screening, most work in this area is dated by nearly a decade. Third, very little information exists regarding

implementation of brief counseling, referral to treatment, or willingness to engage in other point-of-care interventions addressing substance misuse and its associated harms. Finally, and perhaps the most notable gap, is the lack of information regarding dentists' training, motivational factors, and practice behavior related to screening implementation with adolescent patients.¹⁰²

To address these gaps, the proposed Substance Use Disorders Screening study will conduct a national survey of dental practitioners' current substance use screening practices among adolescent and adult patients through the Network. Results of this survey will speak directly to implementation gaps and could inform the development of training and implementation interventions that provide dentists with the necessary tools to implement universal substance use screening, brief interventions, and referral to treatment (when appropriate) confidently and competently.

2.3 Potential Risks and Benefits

This study consists of a cross-sectional, single time point self-report assessment of dental providers. The study (questionnaire) will be applicable to National Network dentists only and will not include patient recruitment. National Network member dentists, both generalist and specialist, who are eligible to participate in Network questionnaires and complete enrollment data will be invited to participate without exclusion based on race, ethnicity, or age. No PHI is collected as part of this study.

2.3.1 Potential Risks

This study poses minimal risk to participants. Study participation is completely voluntary, and participants may discontinue participation at any time without prejudice. As with any study, there is the potential for loss of confidentiality. Appropriate precautions will be taken to mitigate this risk. These precautions include the use of unique study identifiers for participants when linked with questionnaire data, as well as standard use of 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 personnel and will be stored and coded according to guidelines set forth by the overseeing IRB.

2.3.2 Potential Benefits

Participating dentists have the potential to directly benefit from their reflection on their own knowledge and implementation of substance use screening as they respond to items on the questionnaire. As an indirect benefit to participation, knowledge obtained from the questionnaire has the potential to guide development of future training and implementation tools for use in the dental setting. This questionnaire is intended to provide information regarding existing clinical practices pertinent to addictions screening, brief intervention, and referral to treatment in the dental setting. Dissemination of research results beyond study participants may also benefit the broader dental care community.

3 OBJECTIVES AND OUTCOME MEASURES

3.1 Primary

Objective	Brief Description/Justification of Outcome Measure	Outcome Measured By	Time Frame
<p>The primary objective of this study is to conduct a national survey of dentists to assess knowledge, attitudes, and behaviors related to substance use screening implementation among adolescent, young adult, and adult dental patients.</p>	<p>Although dentists regularly encounter patients with problematic substance use and recognize the importance of screening for substance abuse, they have limited exposure to addictions training and generally lack systems to aid in screening, intervention, and referral to addictions treatment.</p> <p>Self-reported knowledge (prior training experiences), attitudes, and current behaviors regarding screening implementation are critical to understand in guiding development of future training and implementation initiatives.</p>	<p>The primary outcome measures will be assessed by an electronic questionnaire regarding current perspectives and practice behavior related to substance use screening among patients.</p> <p>Specific items (or groups of items) will assess each domain with either dichotomous, Likert scale, frequency, or percentage ratings.</p>	<p>Administration of an electronic questionnaire will be used to measure this outcome.</p>

3.2 Secondary

Objective	Brief Description/Justification of Outcome Measure	Outcome Measured By	Time Frame
<p>The secondary objectives are to identify practitioner- and practice-level facilitators and barriers of substance use screening implementation and implementation of early intervention and/or referral strategies (when indicated).</p>	<p>Updated knowledge regarding barriers to screening implementation, particularly implementation among adolescent patient populations, is a critical scientific gap necessary to inform targeted implementation interventions in this arena.</p>	<p>The secondary outcome measures will be assessed by responses provided to an electronic questionnaire regarding practitioners perceived facilitators and barriers to implementing substance use screening, brief intervention, and referral strategies.</p>	<p>Administration of an electronic questionnaire will be used to measure this outcome.</p>

4 STUDY DESIGN

This study is a cross-sectional questionnaire of Network dentists (N=825) practicing across all practice-setting types across the United States. To be eligible for the study, dentists must be enrolled in the Network at Level 2 (limited) or Level 3 (full) participation, currently practicing, and have completed the Enrollment Questionnaire since the start of cycle 3.

The study population will include a stratified random sample of eligible Network dentists. The study sample will be stratified by region. The NCC will be responsible for randomly selecting dentists from within each Network region in proportion to that region's representation in the Network. Network regional quotas will help to ensure that each region has adequate representation within the questionnaire. To provide adequate representation of practitioners working with adolescent patients, pediatric dentists will be oversampled to ensure that a minimum of 50 pediatric dentists participate in the questionnaire.

Eligible Network dentists will be sent an email invitation to participate in the questionnaire study. The questionnaire will take approximately 25-30 minutes to complete and will be administered using the Electronic Data Capture System (EDC) housed at the NCC.

Following the launch of the questionnaire, approximately 50 of the initial questionnaire 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

A participant must meet all the following criteria:

- Is enrolled in the Network as limited or full network member.
- Has completed or updated an Enrollment Questionnaire within cycle 3.
- Is a dentist licensed in the US to treat patients and treats patients in the US on a recurring basis and is able to receive emails and access online questionnaires.

5.1.1 Participant Exclusion Criteria

Participants are excluded from the study if they:

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

5.2 Strategies for Recruitment and Retention

Recruitment

As of November 6, 2022, the Network reported 8,077 enrolled dentist (in solo practice) members. Of the dentist members, only 2.7% (221 dentists) endorse a specialty practice in pediatric dentistry. If randomly sampled proportionate to their representation in the Network, fewer than 25 pediatric dentists would likely complete the questionnaire. Given the keen interest in substance use screening implementation among adolescent patients, we will intentionally oversample pediatric dentists for participation in this study (n=50).

The study population will include a stratified (based on regional membership) random sample. Eligible Network dentists will be identified by the network practitioner database managed by the NCC. A random selection of eligible Network dentists will be invited to participate, using a randomized denominator file. The study will target a sample size of 825 dentist participants.

Dentists will be recruited primarily through email containing a brief description of the study and a link to the study questionnaire. Meetings will be held with Regional Node Coordinators to review recruitment issues and enrollment progress and strategize follow-up methods to enhance participation toward achievement of targeted recruitment.

We will recruit a target of 50 responders to participate in a survey retest within approximately 1-2 weeks of completing the questionnaire to measure item internal validity.

Compensation

Participants who wish to receive compensation and can 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 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

It is anticipated that participants will not be replaced since the invitation numbers are based on prior Network recruitment experience. Participants who withdraw participation prior to completion of the questionnaire will not receive remuneration. Practitioners who contact network staff requesting withdrawal from further SUDS activities will be placed on a do not contact list and removed from study-related email communications.

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.
- Determination of unexpected, significant, or unacceptable risk to study participants.

6 STUDY SCHEDULE

6.1 Phase 1, 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 stratified random sample will be taken. The sample will be stratified based on regional membership to ensure representation of practitioners across the US. To provide adequate representation of practitioners working with adolescent patients, pediatric dentists will be oversampled.
- 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 sampled for the retest until n=50 retest completions are achieved.
- Completion of the retest questionnaire will indicate implied consent.

6.2 Phase 2, 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

This questionnaire was developed through an iterative process that consisted of: (1) a scoping literature review; (2) development of a brief overview of the state of science related to substance use screening recommendations in outpatient healthcare settings; (3) formation of an ad-hoc advisory board consisting of the Network PEC and ad-hoc members with relevant expertise in substance use screening in dental settings; (4) solicitation of key topics to be covered and questions to be answered by the practitioner questionnaire from the Advisory committee; and (5) consultation with topical experts in adolescent substance use screening and assessment. Once the questionnaire items were drafted, it was submitted for full Advisory Board review and edited until a consensus document was developed. This consensus document was reviewed and approved by the NIDCR program official. 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.

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.) and other approved Network collaborators will be given the opportunity to externally test the website prior to administration to study participants.

Questionnaire Administration

According to the inclusion criteria, eligible participants, i.e., Network dentists will be identified from their responses to the Network's enrollment questionnaire.

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 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. Node Coordinators may also contact participants as part of data cleaning conducted by the NCC. Once target recruitment is achieved (N= 825 Dentists), the questionnaire will be closed to participation.

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 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

The primary objective of this study is to conduct a national survey of dentists to assess knowledge and behavior related to substance use screening practices. As such, formal hypothesis testing will not be conducted to achieve the study objectives.

11.2 Sample Size Considerations

Given that the primary analysis is descriptive, the power analysis was based on generating 95% confidence interval widths (i.e., margin of error typically reported with survey and polls) with 80% power. With a sample size of 825 participants, means will have 95% confidence interval widths of .136 standard deviation units (i.e., \pm .068 standard deviation units around the mean). Because confidence interval widths for proportions are dependent on the value of the proportions, we estimated the widths for proportions of 0.10, 0.25, 0.50, 0.75, and 0.90. These estimates are listed in the table below:

Proportion	95% Confidence Interval	
.100	.080	.123
.250	.221	.281
.500	.465	.535
.750	.719	.779
.900	.877	.920

All power analyses were carried out using PASS 2023.¹⁰⁷

11.3 Final Analysis Plan

The primary analysis will be descriptive in nature. For every item on the survey, we will calculate descriptive statistics in the form of frequencies and relative frequencies for categorical variables and means, medians, and standard deviations for continuous variables. We will also calculate the margin of error for each item based on 95% confidence intervals. The items on the survey focus on the following research question domains:

1. What is the frequency of screening, counseling, and referral for each substance category?
2. Who is primarily responsible for screening and counseling in practice?
3. What barriers to screening practices are most commonly identified for each substance type?
4. What facilitators of screening practices implementation are the most endorsed?
5. What is dentists' willingness to engage with point of care interventions (naloxone, NRT)?
6. What is the extent of prior training and willingness to engage in future training?

For the first 4 questions, we will report responses germane to adolescent and adult patients separately.

Secondary Objectives: This study has two secondary objectives. Analysis plans for each objective are detailed below:

- (1) *Determine whether practitioner and practice characteristics are associated with implementation of screening, counseling, and referral.*

To determine whether practitioner characteristics (including age, sex, and race) and practice characteristics (including setting, practice scope, practice region, practice patient age, practice patient race, and number of patients per week) are related to items focusing on screening, counseling, and referral, we will use Fisher's Exact Test for nominal variables and Spearman and Pearson correlations for ordinal and interval/ratio level variables, respectively. Given the large number of items, we will also consider whether items can be summarized using scores based on data reduction techniques such as principal components analysis or principal-axis factor analysis. If the data do not support the use of summary scores, we will use the Benjamini–Hochberg procedure to adjust for the false discovery rate of the p-values resulting from multiple testing.

- (2) *Determine whether there are differences between adults and adolescents on the extent to which substance use is perceived as problematic.*

We will use paired-sample t-tests to account for the same participant providing both ratings on the adolescents and adults and to test whether there is a difference on the degree to which tobacco/nicotine, alcohol, cannabis, and illicit drug use is problematic. Given that the outcomes are rated on an ordinal scale, we will also perform a sensitivity analysis using the Wilcoxon Signed Rank test.

Exploratory Objective: *Are there profiles of screening behaviors across the four substance categories?*

To determine whether there are profiles among the screening behaviors across the four substance use categories, we will use hierarchical cluster analysis. We will choose the optimal linkage/method and similarity/distance measure based on the characteristics of the data. We will select the number of clusters based on the examination of the agglomeration schedule, selecting a range of solutions for further inspection based on the magnitude of dissimilar clusters being combined. We will then compare these profiles, both on the levels of screening behaviors that were inputs into the analysis as well as practitioner and practice characteristics that were external to the formation of the clusters. Selection of the final solution will be based on maintaining both interpretability and parsimony. This analysis will be performed separately for adolescents and adults.

Note that all analyses assume independence of observations by ignoring the clustering effect of providers nested within clinics. The degree to which any inferential analyses are

valid will be dependent on the size of the intraclass correlation and the number of dentists that belong to the same clinic.

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. If the proportion of missing data is very small, we will rely on case-wise analysis.

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

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