A Clinic Randomized Trial of Clinical Decision Support System to Improve Dental Provider Delivery of Brief Tobacco Interventions and Quitline Referrals

NCT NUMBER: NCT03656874

CONSENTS:

HP Provider Consent_21Nov2019_v3

Patient Verbal Consent Survey_1Oct2018_v2

IU Provider Consent

UPitt Provider Consent

HealthPartners Institute

HealthPartners, Inc.
Consent to Participate in a Research Study for Dental Practitioners

Study Title	Engaging Patients in Tobacco Cessation in Dental Settings (ENGAGE)
Study Investigator	D. Brad Rindal, DDS, Senior Research Investigator, Health Partners Institute Daytime phone: 952-967-5026
Study Team Coordinator	Emily Durand, RDH, Principal Project Manager, Health Partners Institute Daytime phone: 952-967-7404 Mobile: 651-262-8736
Sponsor	National Institutes of Health, National Institute of Dental and Craniofacial Research

Background Information/ Why am I being asked to participate?
We would like to ask you to take part in a research study being conducted by the HealthPartners Institute.

Who is sponsoring this study? The HealthPartners Institute is receiving financial support from the National Institutes of Health, National Institute of Dental and Craniofacial Research ("the Sponsor") to assist in conducting this research study.

What is the purpose of the study? The purpose of the study is to better understand dental providers' approaches to assisting patients with tobacco cessation and to examine the effect of an evidence-based clinical decision support (CDS) tool integrated into the Dentrix, EagleSoft or Open Dental electronic dental record (i.e., electronic patient chart) in your clinic.

- We want to quantify the difference in tobacco cessation methods of providers who do versus do not have access to the CDS tool to assist them. This difference in methods will be measured by patients' reports of what occurred during the visit. This information will be obtained by study team members by contacting your patients and inviting them to complete a follow-up phone survey approximately 1 week after and again 6 months after a dental visit with you at which the patient is identified as a current cigarette smoker.
- We also want to quantify differences in knowledge, skills, and attitudes about tobacco cessation among dental providers which may help explain the different methods used. To achieve this, we will provide you with a questionnaire about your attitudes and beliefs about tobacco cessation before the study and again after patients are done being enrolled in your clinic. You are eligible to participate because you are a practicing dentist or dental hygienist seeing patients regularly for routine care with an electronic dental record used in your clinic at the point of care.

Where will this study take place? This study will take place at approximately 20 private practice settings. We expect to enroll approximately 700 patients total across these sites.

What is involved?

For this study, you are being asked to complete an online pre- and post-study dental provider survey about your knowledge, skills, and attitudes about tobacco cessation. Completion of these surveys should take between 10-20 minutes.

You will also be asked to watch a 7-minute online educational video that explains the current Clinical Practice Guideline on Treating Tobacco Use and Dependence.

Depending on whether you are assigned to the CDS or usual care group (see below), you will see patients as usual or with the assistance of the CDS tool. Patients who currently smoke may be contacted by phone within 1-7 days of their dental visit by the HealthPartners Institute Survey Research Center (SRC) and asked to answer a few questions regarding their dental visit and actions they may have made to quit or reduce tobacco use. Patients who agree to follow up will also be contacted at 6 months and asked to answer a few questions regarding actions they may have made to quit or reduce tobacco use.

Random Assignment to CDS or Usual Care

Clinics will be randomly assigned to a study arm (CDS or usual care) like the flip of a coin.

Training. You will be asked to complete a 45-minute training session to learn how the study tool integrates with the electronic dental record in your clinic. You will have the opportunity to ask questions during the training session.

Activities Specific to the CDS Group

CDS application. When you assess patients' tobacco status during their dental visit, the CDS tool will prompt you with scripted messages based on the *5 A's* of Tobacco Cessation (ask, advise, assess, assist, and arrange) and prompts for motivational interviewing techniques. You may use checkboxes to indicate which scripts and patient resources were delivered during the patient encounter. Using this information, the CDS tool will create an automated "smart note" to efficiently document the activities and for use in follow-up during future encounters with the patient. You may use the CDS as you see fit for the specific patient encounter.

Are there any risks to me? The risks in this study relate to confidentiality. All efforts will be made to ensure that no breach of confidentiality occurs. We will reduce this risk by using a practitioner study ID number instead of your name. Patients will also receive a study-specific ID that is not their chart number or otherwise identifying.

Are there any benefits to me? You will not receive any direct benefit by participating in this research. However, your participation in this project may provide valuable information which may improve patient care. All findings will be reported anonymously and in the aggregate, using statistical summaries. If you like, we can compare your clinic results to all the other clinics who participate in this study and report back to you. This would be done anonymously with no identification of the other clinics participating in this study.

Are there any costs or payments for participating? You will be compensated with a $50 Target card for participating. You will also receive a $25 Target card for each of up to 20 eligible patients per year that authorize secondary disclosure of their contact information. Each participating clinic will also receive a

$100 Target card when the study is complete in that clinic. There will also be no cost to you for participating. Patients who complete the telephone surveys will be compensated for their time: $25 for completed baseline surveys and $25 for completed 6-month surveys. You will not be responsible for managing compensation to patients.

Will my records be kept confidential? Information that you provide in the baseline and 6-month surveys will be kept confidential to the extent allowed by law. However, research information that includes your practitioner study ID may be shared with the Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including the sponsor of this study (National Institute of Health). The results of the research may be published for scientific purposes. However, your identity will not be revealed. To help us protect your privacy, a Certificate of Confidentiality has been issued from the National Institutes of Health (NIH). With this Certificate, we can't be forced by a court order or subpoena to disclose information that could identify you in any civil, criminal, administrative, legislative or other proceeding. There are circumstances where the Certificate doesn't protect against disclosure of your personally identifiable information:

- when the US government is inspecting or evaluating federally-funded studies
- when information must be disclosed to meet FDA requirements
- if you give someone written permission to receive research information or you voluntarily disclose your study information
- if the researcher reports that you threatened to harm yourself or others
- in cases of child abuse reported by the researcher
- if the investigator reports cases of contagious disease (such as HIV) to the state

Do I have to be in this study?
You do not have to be in this study. If you start the study, you may stop at any time. There is no penalty or loss of benefits if you don't want to participate, and your decision won't affect your relationship with your employer, the institutions sponsoring or conducting the research, or your EHR software entity. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

Who oversees this study? HealthPartners Institutional Review Board (IRB) has approved this study. The IRB is a group of people who review all research studies at HealthPartners to check that they meet federal laws and ethical standards. IRB approval only means it is ok for the study to begin. Only you can decide if being in this study is the right decision. Feel free to talk about this study with your staff, colleagues and/or patients before you decide.

Who do I contact? If you have any questions, concerns, or complaints about the research, please contact Brad Rindal, DDS at 952-967-5026 (or d.brad.rindal@healthpartners.com) or Emily Durand, RDH at 952-967-7404 (or emily.c.durand@healthpartners.com). If you have any questions about your rights as a research participant, or concerns or complaints about this research you may contact the HealthPartners Institutional Review Board at 952-967-5025.

Copy of Consent Form:
You will be given a copy of this consent form to keep.

Completed electronically with e-signature via secure RedCap study application.

ENGAGE Survey Phone Script

PART A

Hello, is [RESPONDENT] available?

If no: ask for a better time to call back.

If yes: continue…

After establishing that you have [RESPONDENT] on the phone ask: Good morning/afternoon/evening; this is [INTERVIEWER] calling from HealthPartners Institute. I am calling on behalf of [INSTITUTION OR CLINIC NAME] about a research study we are doing at HealthPartners Institute called the ENGAGE study. This is a research study designed to understand how dental providers talk to their patients about tobacco. If you qualify, we would ask you to complete a 5 minute survey over the phone about your most recent dental visit and your health behaviors right now and then again in 6 months. You would receive a $25 Amazon.com Gift Card for this survey and another gift card for the 6-month survey. Are you interested in seeing if you might be eligible?

If no: Thank and end call.

If yes: continue to part B…

PART B

1. Can you confirm that you had a dental visit with [dentist] at [clinic name] on [visit date]?
   If no: Thank and end call (see Part C – Ineligible).
   If yes: continue to Q2

   (Note to interviewer: patients do not need to confirm date and provider of appointment. It is enough that they confirm a recent dental appointment at the clinic.)

2. Can you tell me if you smoke cigarettes or you have smoked cigarettes in the last 30 days?
   If no: Thank and end call (see Part C – Ineligible).
   If yes: continue to Part C - Eligible

PART C – INELIGIBLE (if no to *either* question 1 or 2)

I'm sorry, but you are not eligible for this study. We thank you for your interest and your willingness to talk to us today. Thanks and have a great day.

PART C – ELIGIBLE (if yes to questions 1 and 2)

You are eligible to participate in this study. Participating is completely voluntary and will not affect the care provided by your clinic, insurance coverage or your relationship with your healthcare providers. All information including names will be kept confidential. Are you interested in learning more?

If yes: continue…

If no: Thank you very much. We appreciate your consideration.

Great! Thank you for your time.

You're being invited to participate because you had a visit with a study-participating dental provider, and you meet the eligibility criteria. The purpose of the study is to explore how dental providers talk to their patients about tobacco. We expect the study will include several hundred dental providers and

about 1,400 patients. For this study you are being asked to complete a 5-minute telephone survey now and again in approximately 6 months.

There is no risk or discomfort expected as you answer the surveys. You do not have to answer any questions you do not want to. You will not benefit from participating in this study. The information gathered may help to improve the care provided to future patients.

There are no costs to you. You will be compensated for your time with a $25 Amazon.com Gift Card for completing the survey today and a $25 Amazon.com Gift Card for completing the 6-month survey.

Your information will be kept confidential. Your survey will be assigned an ID number and no information collected from you will be released or made public in association with your name. The results of the study will be published.

You do not have to be in this study. If you start, you may stop at any time. Your decision to participate or not won't affect your relationship with your dental provider or clinic or the institutions sponsoring or conducting the research.

Dr. Brad Rindal at HealthPartners [and Dr. XXX at XXX] is [are] the lead investigator(s) on this study. The study has been reviewed by the HealthPartners Institute Institutional Review Board, which is a group that reviews studies to be sure they are conducted safely and ethically. If you choose to participate, we will send you more information about this study by mail.

If you agree to participate, we will go through the survey together**.**

Are you interested in participating?

If yes: Great! Thank you.
Continue to Part D…
If no: Thank you very much for your time today. We appreciate your consideration.

Part D

We are going to start the survey now. The questions refer to your visit on [visit date] with [dentist] at [clinic name]. Please answer as honestly as you can. There are no right or wrong answers.

Continue to survey…

INDIANA UNIVERSITY STUDY INFORMATION SHEET FOR

A Clinic Randomized Trial of Clinical Decision Support System to Improve Dental Provider Delivery of Brief Tobacco Interventions and Quitline Referrals

You are invited to participate in a research study that seeks to examine dental provider's delivery of a smoking intervention, driven by health information technology (HIT) clinical decision support (CDS) system. You were selected as a possible subject because you are currently a student taking part in an IUSD predoctoral clinic or an IUSD Dental hygiene clinic. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

Dr. Laura Romito, Indiana University School of Dentistry Department of Biomedical and Applied Sciences, is conducting the study. The National Institute of Dental and Craniofacial Research is funding it.

STUDY PURPOSE
The purpose of this study is to examine the rate at which dental providers deliver a smoking intervention and refer to a quitline when their electronic dental record (EDR) system includes health information technology (HIT)-driven clinical decision support (CDS) compared with providers in control clinics without assistance from CDS.

PROCEDURES FOR THE STUDY:
If you agree to be in the study, you will do the following things:

1. Complete pre-study dental provider survey about your knowledge, skills, and attitudes about tobacco cessation.
2. You also will be asked to complete a similar post-study survey six months from now. Completion of these surveys should take between 10-20 minutes.
3. You also will be asked to watch a 30-minute online educational video that explains the current Clinical Practice Guideline on Treating Tobacco Use and Dependence.
4. Depending on whether you are assigned to the CDS or usual care group, you will be asked to participate in a training session designed to train and standardize usage of the CDS tool.
5. Depending on whether you are assigned to the CDS or usual care group, you will see patients as usual or with the assistance of the CDS tool. One week after you have seen a given patient who is a smoker, that patient will be contacted by phone by the HealthPartners Institute Survey Research Center (SRC) and asked to answer a few questions regarding the dental clinic visit during which you saw them.
6. Depending on whether you are assigned to the CDS or usual care group you will be recorded to monitor for fidelity of the intervention if environmental noise levels allow for it.

Random Assignment to CDS or Usual Care
Predoctoral clinic modules will be randomly assigned to either the CDS study arm or the usual care study arm, with two modules being assigned to each arm. Thus, you will be participating in either the CDS or usual care group depending on how the module to which you are assigned has been randomized.

Activities Specific to the CDS Group
Training. If the module to which you are assigned has been randomized into the CDS group, you will be asked to complete another 30-minute training session to learn how the CDS tool integrates into your axiUm electronic dental record. You will have the opportunity to ask questions and practice using the tool on test cases before you use it while providing care.

CDS application. The CDS tool will be triggered when you ask your patients about smoking status as part of their health history update. The CDS tool will prompt you with scripted messages based on the *5 A's* motivational interviewing technique: ask, advise, assess, assist, and arrange. Based on smokers' responses to baseline questions, you will use checkboxes (within axiUm) to choose which personalized scripts and patient resources to deliver during the patient encounter. Using this information, the CDS tool will create an automated "smart note" to efficiently document the activities and for use in follow-up during future encounters with the patient.

RISKS AND BENEFITS
The risks of participating in this research is risk of loss of confidentiality of study data. To reduce this risk, no identifying information on your performance with respect to the clinical domains addressed in this study or on any other aspect of care gathered as part of this research project will be made available to leaders or managers who make academic, employment, compensation, or disciplinary decisions.

You are not expected to benefit from participating in this research; however, the CDS system is designed to encourage smoking cessation conversations in the dental setting and thus may familiarize you with new information that can improve the clinical care you deliver in the present or the future

CONFIDENTIALITY
Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published and databases in which results may be stored. If you are recorded, recordings – video and/or audio – will be accessed by study personnel only and used for validity/fidelity of the study. In compliance with state law, data will be kept archived for 7 years after the study has been finalized.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, the study sponsor, The National Institute of Dental and Craniofacial Research, Health Partners Institute, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP), the National Cancer Institute (NCI), the National Institutes of Health (NIH), etc., who may need to access your research records.

PAYMENT
You will receive a 50 dollar gift card from HealthPartners Institute upon the completion of the 6 month provider survey.

CONTACTS FOR QUESTIONS OR PROBLEMS
For questions about the study, contact the researcher Dr. Laura Romito at 317-278-6210. For questions about your rights as a research participant or to discuss problems, complaints or concerns about a research study, or to obtain information, or offer input, contact the IU Human Subjects Office at (317) 278-3458 or (800) 696-2949.

VOLUNTARY NATURE OF STUDY
Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with Indiana University School of Dentistry.

Printed Name:_____

UNIVERSITY OF PITTSBURGH
School of Dental Medicine

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

STUDY TITLE: A Clinic Randomized Trial of a Clinical Decision Support System to Improve Dental Provider Delivery of Brief Tobacco Interventions and Quitline Referrals

PRINCIPAL INVESTIGATOR: Jean A. O'Donnell, BSN, MSN, DMD
Associate Professor/Associate Dean for Academic Affairs
440 Salk Hall
3501 Terrace Street
Pittsburgh, PA 15261
Phone: 412-648-8672
Email: jao4@pitt.edu

QUESTIONS ABOUT THE STUDY:

If you have any questions, concerns, or complaints about this research study, you may contact the Principal Investigator, Dr. Jean O'Donnell, using the contact information listed above or the Study Coordinator, Dr. Denise Deverts, at 412-624-7387 or dlj43@pitt.edu.

If you have any questions about your rights as a research subject or wish to talk to someone other the research team, please call the University of Pittsburgh Human Subjects Protection Advocate toll-free at 866-212-2668.

SOURCE OF SUPPORT:

This research study is being funded by National Institute of Dental and Craniofacial Research (NIDCR) 1 U01 DE026135 01.

SIGNIFICANT FINANCIAL CONFLICT OF INTEREST:

The Principal Investigator and members of the study team declare no conflicts of interest.

INTRODUCTION:

You are being asked to take part in a research study conducted by HealthPartners Institute for Education and Research in collaboration with the University of Pittsburgh School of Dental Medicine and the Indiana University School of Dentistry. Before you decide to participate in this study, it is important that you understand why the research is being done and what your participation in it will involve. Please read the following information carefully. If anything is not clear or if you need additional information, please feel free to ask a member of the study staff.

The purpose of this research study is to examine the rate at which dental providers deliver a smoking intervention and refer to a quitline when their electronic dental record (EDR) system includes health information technology (HIT)-driven clinical decision support (CDS) compared with providers in control clinics without assistance from CDS.

You are being invited to participate in this research study because you are either a third or fourth year predoctoral dental student or a second year student of dental hygiene at the University of Pittsburgh School of Dental Medicine.

We anticipate that a total of 400-500 student providers will take part in this study, including approximately 200 student providers from this institution.

The duration of your participation in this study will be approximately 6 months.

RESEARCH ACTIVITIES:

For this study, you are being asked to complete pre-study dental provider survey about your knowledge, skills, and attitudes about tobacco cessation. You also will be asked to complete a similar post-study survey six months from now. Completion of these surveys should take between 10-20 minutes.

You also will be asked to watch a 30-minute online educational video that explains the current Clinical Practice Guideline on Treating Tobacco Use and Dependence.

Depending on whether you are assigned to the CDS or usual care group (see below), you will see patients as usual or with the assistance of the CDS tool. One week after you have seen a given patient who is a smoker, that patient will be contacted by phone by the HealthPartners Institute Survey Research Center (SRC) and asked to answer a few questions regarding the dental clinic visit during which you saw them.

Random Assignment to CDS or Usual Care

Predoctoral clinic modules will be randomly assigned (coin-flip) to either the CDS study arm or the usual care study arm, with two modules being assigned to each arm. Thus, you will be participating in either the CDS or usual care group depending on how the module to which you are assigned has been randomized.

Activities Specific to the CDS Group

Training. If the module to which you are assigned has been randomized into the CDS group, you will be asked to complete another 30-minute training session to learn how the CDS tool integrates into your axiUm electronic dental record. You will have the opportunity to ask questions and practice using the tool on test cases before you use it while providing care.

CDS application. The CDS tool will be triggered when you ask your patients about smoking status as part of their health history update. The CDS tool will prompt you with scripted messages based on the *5 A's* motivational interviewing technique: ask, advise, assess, assist, and arrange. Based on smokers' responses to baseline questions, you will use checkboxes (within axiUm) to choose which personalized scripts and patient resources to deliver during the patient encounter. Using this information, the CDS tool will create an automated "smart note" to efficiently document the activities and for use in follow-up during future encounters with the patient.

STUDY RISKS:

If you choose to participate in this research study, risks to you will be minimal and involve only the risk of violation of confidentiality of study data. To reduce this risk, no identifying information on your performance with respect to the clinical domains addressed in this study or on any other aspect of care gathered as part of this research project will be made available to leaders or managers who make academic, employment, compensation, or disciplinary decisions.

STUDY BENEFITS:

You likely will not derive any personal benefit from participating in this research study. However, the CDS system is designed to encourage smoking cessation conversations in the dental setting, and thus may familiarize you with new information that can improve the clinical care you deliver in the present or the future.

NEW INFORMATION:

You will be promptly notified if any new information we learn during this research study may cause you to change your mind about continuing to participate in the study.

CONFIDENTIALITY:

The confidentiality of your data will be ensured by assigning an arbitrary and unique subject identification number to each participating student provider. All data collected in this research study will be identified by subject identification (ID) number only. No participant data will be individually identified or released to anyone other than the study investigators (see exceptions below) without specific written permission from the study participant. A file containing a link between the study ID and individually identifying information will be maintained by the local study coordinator. All electronic study data will be maintained by HealthPartners Institute in a secure, computerized database residing on a username and password protected-access fileserver to which only the researchers involved in the study will have access. Access privileges will be role-dependent. All-study related paper documents containing individually identifiable information will be maintained locally in a locked file cabinet in a physically-secured research office in Salk Hall.

Per University of Pittsburgh policy, all research records must be maintained for at least 7 years following final reporting or publication of a project.

All findings will be reported anonymously and in the aggregate, using statistical summaries. If you like, we can compare your results to all the others who participate in this study and report back to you. All information included in such reports would be anonymous, with no identification of the other clinics participating in this study.

Exceptions

There are a few conditions under which your research information may be released to individuals other than members of the research team:

- We are obligated to release your research information if we receive a request for review from the University of Pittsburgh Research Conduct and Compliance Office
- We likewise are obligated to release your research information if we receive a request for review by the National Institute of Dental and Craniofacial Research (study sponsor)
- If you tell us something that makes us believe that you or others have been or may be physically harmed, we are required by Pennsylvania law to report that information to the appropriate agencies.
- In rare cases, and only if necessary, your research records may be released in response to an order from a court of law.

WITHDRAWAL FROM STUDY PARTICIPATION:

You can withdraw from this research study at any time. Your decision to withdraw from this study will have no effect on your grades or your current or future relationships with your instructors, the University of Pittsburgh School of Dental Medicine, or the University of Pittsburgh more generally. Any identifiable research information obtained as part of this study prior to the date that you withdrew your consent will continue to be used and disclosed by the investigators for the purposes described above.

- To formally withdraw from this research study, you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.
- It is possible that you may be removed from the research study by the researchers. Some potential reasons for terminating a subject's participation in a study include non-compliance with study procedures and subject's deliberate provision of false information.

COSTS AND PAYMENTS:

You will neither incur costs from nor receive payment for participating in any of the activities you perform as a part of this research study.

VOLUNTARY PARTICIPATION:

Your participation in this research study is entirely voluntary. Whether you provide your consent for participation in this research study will have no effect on your grades or your current or future relationships with your instructors, the University of Pittsburgh School of Dental Medicine, or the University of Pittsburgh more generally.

STATEMENT OF CONSENT:

- The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given.
- I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the Human Research Protection Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation.
- By signing this form I agree to participate in this research study. A copy of this consent form will be given to me.

_____

Printed Name of Person Providing Consent

_____ _____

Signature of Person Providing Consent | Today's Date

INVESTIGATOR CERTIFICATION:

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Printed Name of Person Obtaining Consent | Role in Study

_____ _____

Signature of Person Obtaining Consent | Today's Date