November 2nd, 2015

S12-01148

Name of study: Implementing tobacco use treatment guidelines in dental public health clinics

Research Protocol

1. Purpose of the Study and Background

1.a. Purpose of the Study

System level strategies for implementing tobacco use treatment guidelines exist but are insufficiently put into practice, particularly in dental care settings. Closing the gap between research and practice is stymied by the limited research on systems changes necessary to implement tobacco treatment in routine dental care. The purpose of this study is to compare the effectiveness of three systems-level strategies: 1) staff training and clinical reminders, 2) provider feedback and 3) pay-for- performance (financial incentives), on improving provider adherence to guideline recommended tobacco use treatment.

1.b. Background

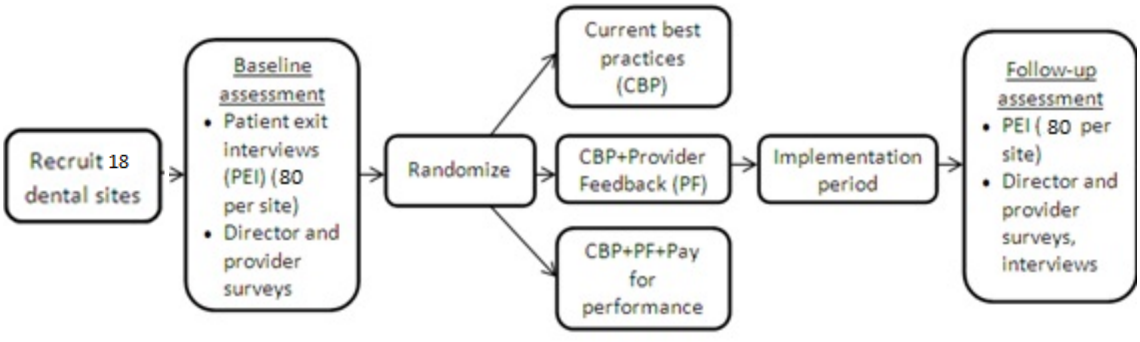
Based on meta-analyses of over 8000 tobacco cessation studies published in the past three decades, the 2008 Public Health Service (PHS) Guideline, *Treating Tobacco Use and Dependence* provides strong evidence that provider delivery of tobacco dependence treatment, including cessation pharmacotherapy and brief counseling, can produce significant and sustained reductions in tobacco use and should be delivered to all smokers seeking routine health care (Fiore 2008). Provider adherence to the PHS Guideline recommendations requires asking all patients about tobacco use, advising smokers to quit, assessing readiness to quit, providing cessation assistance and arranging follow-up (the so-called 5As) (Fiore 2008). Adequate implementation of the PHS Guidelines would generate 1.6 million additional quitters per year and nearly 3.3 million quality life years saved (USDHHS 2000). Unfortunately, delivery of tobacco use treatment in routine dental care remains limited (Albert 2002, Albert 2005, Tong 2010).

National surveys indicate that dental providers are increasingly screening for tobacco use and offering brief advice, adherence to the PHS guidelines in inconsistent with only 10-25% dental health professionals' routinely delivering cessation assistance (e.g. cessation pharmacotherapy prescriptions and/or referral for cessation counseling) (Albert 2002, Tong 2010). Dentists most often cite lack of training, and adequate reimbursement to explain their subpar performance in providing tobacco cessation interventions (Albert 2005). Challenges to wide-scale implementation of tobacco dependence treatment also include a lack of referral resources and a lack of office-based systems (Gordon 2006, Albert 2005). PHS guideline implementation is likely affected by both provider attitudes and organizational priorities that impact provider behavior (Albert 2002, Curry 2000, Fiore 2008).

2. Study Design

We propose a 3-arm cluster randomized controlled trial that will analyze the implementation process and compare the cost and effectiveness of three implementation strategies: 1) Staff training and CBP in implementing PHS Guidelines; 2) CBP + provider performance feedback (PF) and 3) CBP + PF + Pay-for-performance (provider reimbursement for tobacco cessation treatment delivery). Guided by Organizational Change Theory and the Theory of Planned Behavior (Ajzen 1991, Damschroder 2009, Greenhalgh 2004, Solberg 2007) we will identify multi-level factors that facilitate or impede the implementation process in dental clinics. Our primary outcome is improvement in provider delivery of tobacco cessation treatment. Our secondary outcome will be post-intervention patient-reported quit rates. In addition to examining the comparative effectiveness of the three implementation strategies, we will use a mixed methods approach to examine implementation processes (Aim 2) to assess the degree to which the interventions are integrated into practice as intended and to clarify the mechanisms through which the intervention influences provider behavior.

Figure 1. Study Design



3. Characteristics of the Research Population

3.a. Data collection locations:

We plan to enroll 18 public dental health clinics throughout Manhattan, Queens, Brooklyn, and the Bronx as locations for data collection. We expect to include sites that are part of New York University's Clinical and Translational Science Institute (CTSI) which will rely on NYUSoM's Institutional Review Board (IRB), and non-CTSI sites, which may have additional IRB requirements. Dental clinics participating in the study include: Hotel Trades Union Council's Brooklyn Health Center, Hotel Trades Union Council's Midtown Health Center, Hotel Trades Union Council's Harlem Health Center, Gouverneur Health, Metropolitan Hospital, Woodhull Hospital, Queens Hospital Center, Kings County Hospital Center, Coney Island Medical Center, Callen Lorde Community Health Center, Urban Health Plan, Joseph P. Addabbo Neighborhood Health Center, Boriken Neighborhood Health Center, three clinics affiliated with Lutheran Medical Center, and two of Saint Barnabas Hospital's affiliated Union Community Health Centers.

A wave in this study is defined as a set of three study locations that will be randomized to one of the three arms described above. The first three clinics (Wave 1) are part of the pilot phase of the study conducted to test the feasibility of implementing each intervention component presented in this protocol.

3.b. Number of Subjects

Patients: We expect to enroll 80 smokers pre and post-intervention at each of the 18 public health dental clinic study sites (a total number of 2880 patients, 1440 at baseline and 1440 post-intervention). We calculated statistical power to ensure sufficient sample size to address the key components of study aims.

Providers: We expect to enroll approximately 30 dental providers, including one dental director, at each site for a total of 540 dental providers and 18 dental directors. The final number of participating providers from each site will vary depending upon the size of the dental practice,

3.c. Gender of Subjects

We expect equal distribution of both men and women in this study.

3.d. Age of Subjects

All subjects will be 18 or older

3.e. Racial and Ethnic Origin

The racial and ethnic origin will parallel that of the clinicians and staff at participating sites, and the patients who seek treatment in their clinics.

3.f. Inclusion Criteria

Patient eligibility: 1) age 18 or over; 2) active smokers defined as those who report smoking cigarettes some days, most days, or every day and have smoked within the past 7 days; 3) have an appointment with a dentist or hygienist for routine non-emergent care; 4) NYS resident 5) speaks English, Spanish, Chinese or Russian; and 6) able to comply with the study procedures in the opinion of the principal investigator.

Provider eligibility includes being a full-time or part-time practicing dental provider at one of the study sites.

Clinic location eligibility includes public dental clinics that are located within the NYC metropolitan area that employee at least three FTE dentists.

3.g. Exclusion Criteria

Patients are excluded if: 1) they do not speak English, Spanish, Chinese, or Russian; 2) they have an emergency care appointment; 3) they have already completed the patient exit interview during the same intervention phase.

Providers are excluded if they do not speak English.

Clinic locations are excluded if the number of unique adult patient visits per week averages less than 100, if the dental director reports that the clinic assists more than 60% of patients with tobacco cessation and if the clinics policies would prohibit the clinic from accepting pay-for-performance funds if randomized to that arm.

3.h. Vulnerable Subjects

None

4. Methods & Procedures

4.a. Sources of Research Material

Patient source materials include a cross-sectional survey referred to as the Patient Exit Interview (PEI) conducted immediately after the patient visit and a 3 month follow-up telephone survey ONLY in the post intervention period.

Patient Exit Interview: Patient exit interviews will be administered at baseline and about 9 months following the intervention (pre and post intervention). We will use a slightly modified, 17-item PEI to assess provider adherence to tobacco use treatment guidelines. The PEI is a brief measure that assesses provider adherence to tobacco use treatment guidelines by asking the patient if the provider asked about tobacco use and offered cessation assistance. The PEI will also be used to assess post-intervention patient reported quit rates within the past year. The PEI is administered in person at the clinic by RSA staff from NYU. The survey requires approximately 5 minutes for completion. We expect that most surveys will be administered using a password protected web-based data entry portal. However, RSAs will have printed versions of the survey onsite for those participants who express discomfort with the computer tablet interface. In order to anonymously link patient reports of provider behavior to individual providers, study RSAs will record which provider each participant saw during their visit on the PEI. Study staff will have a list of each provider and a corresponding, de-identified provider ID. The list of provider IDs will be kept in a secure location and only research study staff will have access to this list.

Provider Source Materials

We will be asking all the dental providers (dental directors, dentists, dental hygienists, dental residents, dental assistants) to complete three surveys: baseline (pre-intervention) and two follow up surveys at 4.5 months into the intervention period and at 9 months (end of intervention). Dental providers will be invited to participate in the provider surveys in one of two ways: 1) through a secure link sent via email through REDCap or 2) on paper. Two survey methods are offered to accommodate providers and to increase potential participation. Participants who do not complete the survey online will be emailed up to two reminders to complete each survey. If it is not possible or preferable for the participant to complete the survey online, and/or if they express discomfort with web-based surveys they will be able to complete the survey on paper. Data captured on paper will be entered into the database by study staff.

Baseline Provider Survey. The Baseline Provider Survey is composed of four sections: demographics, guideline and practice behaviors, attitudes, experiences. This survey takes about 7 minutes to complete. Providers will be asked to complete the follow up provider survey at approximately 4.5 months and 9 months.

Provider demographics: This section consists of ten items and will measure provider characteristics and demographics such as role, degree, years of practice and smoking status. .

Provider Guideline and Practice Behaviors: Eleven items that assess provider's perceptions of the content of tobacco cessation interventions that they provide, and to what percentage of their patients they routinely provide interventions.

Provider Attitudes: The provider attitudes survey draws from three previously validated provider surveys (Amemori 2011, Francis 2008 and Park 2001). The provider survey consists of 40 items for which statements are rated on a Likert scale of 1 (fully disagree) to 5 (fully agree).

Provider perceptions about organizational characteristics: We will use a slightly modified version of the Perceived Organizational Priority Survey (Klein, Conn and Sorra, 2001) to assess the perceived priority of tobacco use treatment at the dental clinic. This is a brief measure that consists of eight statements. Providers will be asked to rate each statement using the following response scale: 1 (not true) to 5 (true). We will also ask six questions (Weiner, 2013) that are designed to assess general experiences of providers in the clinic. For this section, providers are asked to rank statements using the following response scale: 1 (disagree) to 5 (agree).

4.5 and 9 Month Follow Up Provider Survey: The Follow Up Provider surveys consist of the same three content areas as the baseline: guideline and practice behaviors, attitudes, experiences. Providers who did not complete the baseline survey will also be asked to complete the demographic questionnaire described above.

Dental Director Source Materials:

We will also ask a dental director from each site to complete a dental director survey at baseline, 4.5 months, and 9 months that is similar to the provider survey and to participate in a focus group at the end of the intervention period.

Dental Director Baseline Survey: In addition to completing the dental provider surveys, the dental director of each clinic location (n=18) will be asked to complete a clinic characteristics survey and the Change Process Capability Questionnaire for their clinic. These sections will be administered at baseline only and contain questions such as number of dental staff employed by the clinic, patient payer mix, academic affiliation/ownership, panel size and staff characteristics. The Change Process Capability Questionnaire (CPCQ) will be used to assess dental provider's perceptions of the organizations change history, refinement plans, change capacity, and ability to initiate and sustain change (Solberg, 2008). The survey will take about ten minutes to complete.

4.5 and 9 Month Follow Up Director Survey: Similar to the provider surveys the 4.5 and 9 Month Follow Up Director surveys consists of three sections: guideline and practice behaviors, attitudes, perceptions of organizational characteristics. The survey will take about ten minutes to complete.
Guideline and Practice Behaviors: Eleven items that assess directors' perceptions of the content of tobacco cessation interventions that they provide, and to what percentage of their patients they routinely provide interventions. This section will take about two minutes to complete.
Dental director attitudes: The provider attitudes survey draws from three previously validated provider surveys (Amemori 2011, Francis 2008 and Park 2001). The provider survey consists of 40 items for which statements are rated on a Likert scale of 1 (fully disagree) to 5 (fully agree). The provider attitudes section will take about 5 minutes to complete.
Dental Director perceptions of organizational characteristics:
We will use a slightly modified version of the Perceived Organizational Priority Survey (Klein, Conn and Sorra, 2001) to assess the perceived priority of tobacco use treatment at the dental clinic. Providers will be asked to rate each statement using the following response scale: 1 (not true) to 5 (true). We will also ask six questions (Weiner, 2013) that are designed to assess general experiences of providers in the clinic. For this section, providers are asked to rank statements using the following response scale: 1 (disagree) to 5 (agree).

Quitline data: the New York State Quitline will generate a monthly report of the number of fax referral forms they have received from each of the 18 sites and this monthly report will be forwarded to the MSKCC Data Coordinating Center. The reports do not contain any patient information.

Focus Groups:
Focus groups will be held after completion of the intervention period with the dental director and providers at each of the participating dental clinics. The groups will focus on assessing site-specific barriers and facilitators of strategy implementation and the process of integrating the implementation strategy into the workflow and customizing it to the study settings as well as acceptability and satisfaction with the implementation components (e.g. referral system).

4.b. Intervention conditions: Table 1 shows the intervention components within each study arm.

Table 1. Implementation Strategy Components	Arm 1 CBP	Arm 2 CBP + Performance Feedback (PF)	Arm 3 CBP + PF + Pay for Performance (P4P)
1. Staff training on PHS Guideline	X	X	X
2. Chart reminder and documentation system	X	X	X
3. Quitline Fax referral system	X	X	X
4. Tool Kits - Cessation Medication Prescribing Tools - Patient education booklets	X	X	X
5. Quarterly chart audit		X	X
6. Quarterly Performance Feedback reports		X	X
7. Pay for Performance			X

ARM 1: Staff Training and Current Best Practices (CBP). All dental field sites will receive current best practices for training and on-site technical assistance in promoting adoption of clinical practice guidelines for treating tobacco dependence. The CBP tobacco use treatment protocol that will be implemented is consistent with the PHS recommended guidelines and is as follows: The dental care team will assess smoking status, deliver advice to quit, assess readiness to quit, provide patient education materials, a prescription for cessation

pharmacotherapy and referral to the NYS Quitline, and document findings and treatment plan on the chart system. In New York State, all cessation pharmacotherapies are covered by Medicaid and the Quitline provides free medication for those who are uninsured. As brief provider interventions have been shown to be effective, the recommended tobacco treatment protocol will require approximately 5-10 minutes.[1] Details of Current Best Practices (CBP) are summarized as follows:

1. *Staff training:* All clinical (i.e. dentists, dental hygienists, and/or dental assistants) and support staff will be trained over a 1-hour session in the use of the intervention protocol. The training is based on the PHS guideline "Treating Tobacco use and Dependence" and will include prescribing smoking cessation pharmacotherapy, how to use the Refer-to-Quit program, other referral resources, New York State (NYS) health insurance coverage for treatment and a review of the guideline algorithm to stratify patients according to readiness to make a quit attempt (Fiore 2008). A Booster Training will be held approximately half way through the intervention period to reinforce tobacco use treatment and address any patient or workflow barriers to delivering cessation assistance. Additional training sessions will be held as needed for new dental providers who started working at the dental clinics after the initial or booster training. The proposed protocol, including the provision of pharmacotherapy is consistent with American Dental Association (ADA) recommendations (ADA 2008). Moreover, research has demonstrated that cessation training and awareness of the PHS Guideline is associated with higher rates of providers' discussing medication with patients and offering prescriptions (Gordon 2005, Havlicek 2006, Shelley 2010). Trainings will be conducted by Dr. Shelley, Dr. Jamie Ostroff, PhD (Co-Principal Investigator at Memorial Sloan Kettering) and DUET study staff and offered onsite at each individual field site.
2. *Chart Reminder system:* The chart system is designed to remind the clinician to ask those questions required for assessing readiness to quit and to offer each smoker stage specific cessation advice. Drs. Shelley and Ostroff have gained extensive experience working to integrate tobacco use treatment clinical reminder and documentation systems across a wide range of clinical settings. To enhance uptake and sustainability, the chart prompt will be integrated into the existing chart system (i.e. paper or electronic). Most sites already have billing codes for treating tobacco use and the remaining sites have agreed to add chart documentation system and billing codes for tobacco dependence.
3. *Refer to Quit Referral System:* Quitlines substantially increase abstinence rates compared to minimal or no counseling (Fiore 2008). New York State (NYS) began operating a smokers' Quitline in 2000 and receives over 35,000 calls per year (Fiore 2008). The "Refer-to-Quit" program aims to simplify the health care provider referral process by offering clinical practices a way to link patients to a proactive telephone counseling service using a pre-printed fax referral form. Patients who are ready to quit are asked by the dentist to sign a referral form that is faxed by administrative staff to the NYS Quitline. The Quitline makes five attempts to reach patients within one week after receiving the fax or within one week of the quit date, if one is designated on the faxed form. Smoking cessation counselors at the NYS Quitline provide two, 20-30 minute proactive telephone counseling sessions to referred smokers. .
4. *Tool Kits (Education Booklets and Prescribing Tools):* All field sites will receive a tool kit with patient education booklets describing the tobacco-related oral health risks, a laminated pharmacotherapy prescribing information card tailored for dental providers, Refer-to-quit forms, and the brief version of the PHS guideline for Treating Tobacco Dependence (Fiore 2008).

ARM 2: CBP + performance feedback .

Quarterly Performance Feedback Reports: In ARMS 2 and 3 performance feedback is a core component of this quality improvement (QI) intervention as it has been shown to improve provider adherence to tobacco use treatment guidelines (the primary outcome). In order to create the quarterly performance feedback reports we

will conduct chart reviews every three months during the 9 month intervention period (total 3 chart reviews per site). The chart reviews assess if there is documentation that providers have followed guideline recommendations to screen all patients for tobacco use and offer cessation assistance to all smokers. The chart reviews are retrospective, and therefore review only data from patient visits in the previous three months. Since the chart audits are retrospective, it is not feasible to locate each patient seen during the previous quarter to obtain consent.

The dental director will designate a clinic staff member to be trained on generating reports on documented adherence to tobacco use treatment guidelines. If clinic staff cannot perform the chart audits, research staff will conduct the audits. Data extracted through chart reviews is de-identified and aggregated to the provider and clinic level. The Data Coordinator will convert the findings into a graphic presentation displaying each provider's individual performance compared to their peers and to a predetermined performance benchmark. The dental directors will distribute reports to providers at facilities enrolled into the 2nd and 3rd study arms no later than 30 days following the end of the quarter. Research staff will obtain volunteer status at each study site and we will obtain a Business Associate Agreement, signed by NYULMC and the study sites.

ARM 3: CBP + PF + financial incentive (pay for performance, P4P)

Pay for Performance: Field sites randomly assigned to this implementation condition (Arm 3) will receive current best practices, quarterly performance reports, and financial incentives for documenting delivery of adherence to clinical practice guidelines. Given that dental providers in community health centers are salaried employees, the financial incentive will be provided to the organization. Using the same chart auditing procedures described above, we will review charts of all smokers to evaluate documentation of cessation assistance (i.e., prescription given for cessation medication, the provision of brief cessation counseling and/or a fax referral to the NYS Quitline or other local cessation support program). Sites will receive $20 for each patient with chart documentation of receiving tobacco cessation assistance. The P4P reimbursement bonus will be offered quarterly with an annual cap of $5000.

Our P4P procedures including the amount of financial incentive are guided by published work done by Roski (2003) as well as a current demonstration project being conducted by the NYC Department of Health. The incentive amount is also consistent with the current Medicaid and Medicare reimbursement (NYSDOH 2010, Theobald 2006) structure for 10 minutes of smoking cessation counseling and represents an amount that was judged meaningful by members of our advisory committee representing the American Dental Association (Dr. Davis) and the dental insurance industry (Dr. Yamamoto).

5. Data Analysis and Data Monitoring: Statistical Plan

General Approach: The data analysis will be conducted at MSKCC by the designated study statistician, Dr. Yuelin Li, Associate Attending Statistician. The study plans to recruit 18 public health dental sites; the first three will be part of a pilot wave to test the feasibility of the data collection instruments and the intervention components. All 18 public health dental sites will be randomly assigned into one of three implementation strategies (interventions) in a multiple-level, cluster-randomized design. Randomization will occur after collection of 80 patient exit interviews and before implementation period. The general statistical paradigm for assessing outcomes will be based on a Multi-Level Model (MLM) approach (Johnson 1997) (also known as "hierarchical linear model") (Coleman 2010, Laird 1982, Pinheiro 2004, Strauss 2010). MLM adjusts for the clustering effects across multiple levels (patients, providers, dental clinics) of hierarchical data structure. The data structure therefore follows a hierarchy of patient-level data nested within providers, nested within sites and sites randomly assigned to implementation strategy conditions. Before the implementation strategies are

initiated (baseline period), 80 patients per site will be assessed through standardized Patient Exit Interviews to establish the baseline level of dental provider assistance in tobacco cessation. Post intervention we will again recruit 80 patients for assessment of changes in provider adherence to tobacco treatment delivery guidelines. All surveys will be administered to the patients and providers as described above.

Implementation Fidelity. Using the indicators described in the evaluation plan, we will summarize relevant data describing the observed implementation of the intervention strategies (CBP, PF and PFP) so as to support reporting of trial outcomes data consistent with CONSORT guidelines modified for pragmatic practice-based trials (Zwarenstein 2008).

Analytic Strategies Specific to the Research Aims

AIM 1. To compare the effectiveness and cost of three strategies for implementation of the tobacco use treatment guidelines between CBP, CBP+PF, and CBP+PF+P4P.

MLM for the Primary Hypothesis: This is an omnibus test of the effectiveness of the implementation strategies. The primary outcome is the summary score of the Patient Exit Interview assessment of provider delivery of tobacco cessation assistance (score range 0 – 10). This omnibus hypothesis provides the foundation for subsequent pairwise comparisons. A two-level MLM addresses this hypothesis. At level 1, we enter each patient's PEI score of dental provider assistance:

Level 1: $\mathrm{PEI}_{k[i,j]} = \alpha_{k[i,j]} + \beta_{0k[i,j]} \cdot [\mathrm{post} - \mathrm{pre}] + \beta \cdot X_{k[i,j]} + \varepsilon_{k[i,j]},\ \varepsilon_{k[i,j]} \approx N\left(0, \sigma_1^2\right),$

where the bracketed notation k[i, j] represents the hierarchical structure that assessment from the ith patient is nested within the jth dental care provider at the kth site. The dependent variable is the patients' summary PEI score on dental provider delivered cessation assistance. The alpha coefficients represent the assistance for patients assessed before the sites have entered the active intervention phase. The β_0 coefficient represents the change in cessation assistance after the site has entered active implementation as compared to pre-implementation. The inclusion of this [post-pre] dummy variable accounts for pre-implementation differences between sites, if any. This [post-pre] comparison allows each site to serve as its own pre-implementation control, an added benefit to minimize an order effect, e.g., sites that enter the active implementation phase later may derive greater benefits due in part to improved efficiency in logistics coordination. Additional covariates may also be included (e.g., patients' age, gender, and education), using matrix notation in the $\beta \cdot X_{k[i,j]}$ term (Fitzmaurice 2004, Laird 1982, Pinheiro 2004). Inclusion of covariates will be guided by our preliminary analyses to minimize the risk of model over-fit.

The level 1 parameters $\alpha_{k[i,j]}$ and $\beta_{0k[i,j]}$ are further analyzed in a second level model:

Level 2:
$$\alpha_{k[i,j]} = \gamma_{00} + \gamma_{01}\mathrm{Tx}_k + \gamma_{k1}, \qquad \gamma_{k1} \approx N\left(0, \sigma_2^2\right),$$
$$\beta_{0k[i,j]} = \gamma_{01} + \gamma_{11}\mathrm{Tx}_k + \gamma_{k2}, \qquad \gamma_{k2} \approx N\left(0, \sigma_3^2\right).$$

Here, the variable Tx_k represents the randomly-assigned implementation strategy for the kth site. The level-2 model yields an average cessation assistance (γ_{00}) increase due to intervention (γ_{01}), and site-level random effects (γ_{k1}). Similarly, the [post-pre] changes in cessation assistance in level 1 ($\beta_{0k[i,j]}$) is further unpacked into an overall change (γ_{01}) and changes attributable to implementation strategies (γ_{11}). The omnibus hypothesis is supported if there is a statistically significant γ_{01} coefficient by a Type-III Sums of Square F test indicating statistically discernible differences between the three implementation strategies. A significant γ_{11} coefficient will indicate that provider behavior change is significantly associated with implementation strategies.

MLM to address secondary outcomes on smoking abstinence (7 day point abstinence) and utilization of tobacco treatment services: The smoking abstinence and cessation treatment utilization outcomes of all post-intervention patients (80 per site) will be assessed 3 months after the exit interviews, as part of the patient

telephone survey in the post intervention period among all patients who completed the exit interviews. A MLM with a logit link is appropriate to address the dichotomous smoking abstinence outcome:

Level 1: $\Pr(\text{abstinent})_{k[i,j]} = \log^{-1}[\alpha_{k[i,j]} + \beta \cdot X_{k[i,j]} + \varepsilon_{k[i,j]}],\ \varepsilon_{k[i,j]} \approx N(0, \sigma_1^2),$

Level 2: $\alpha_{k[i,j]} = \gamma_{00} + \gamma_{01}\text{Tx}_k + \gamma_{02}\text{PEI}_k + \gamma_{k1}, \qquad \gamma_{k1} \approx N(0, \sigma_2^2),$

where a statistically significant γ_{01}Tx coefficient in Level 2 would support the hypothesis of a differential treatment effect on smoking abstinence and treatment utilization across the three randomized arms. The secondary aim is primarily concerned about abstinence and treatment utilization after the intervention has been completed. Nevertheless, MLM is flexible to account for patients' characteristics (e.g., age, sex, and nicotine dependence in the covariate matrix $[\beta \cdot X_{k[i,j]}]$) as well as sites' characteristics (e.g., baseline PEI for the kth site to minimize the order effect). Inclusions of covariates may reduce residual error and thus boost power.

Cost analysis. We will perform a cost-effectiveness analysis following standard guidelines to assess and compare the value for each intervention arm. We will perform analyses from a societal and payor perspective, as this perspective is sometimes preferred by decision makers. Using patients' reported quit rates from the post-intervention PEI, we will develop a predictive model of expected health and cost outcomes associated with smoking cessation (Petitti 2000, Weinstein 2001). Drawing on the results of the effectiveness analysis and the cost-estimation analyses, we will estimate incremental cost-effectiveness ratios for each of the intervention arms, relative to each other and to the current best practices arm. These data will provide important benchmarks for health policy decision-making on allocation of resources for treatment of tobacco dependence in dental clinics.

AIM 2. To examine potential theory-driven mechanisms at the organizational and provider level hypothesized to explain the comparative effectiveness of three strategies for implementation. This aim addresses research questions related to causal mechanisms and effect modifiers that result in changes in provider behaviors. This aim may also shed new light on implementation fit (i.e. what components of the interventions worked for whom). Aim 2 will be addressed through both qualitative and quantitative methods.

In terms of the qualitative data, raw data obtained from the audio recordings from the focus groups of the dental directors and providers will be transcribed verbatim by an outside transcription vendor (RL Fisher). Led by an experienced Qualitative Methods Specialist (Elyse Shuk) from the MSK Behavioral Research Methods Core, a team of trained and supervised coders will analyze the interview data using an inductive thematic text analysis approach, involving a rigorous review and interpretation of the transcripts to identify key concepts and patterns (Creswell 1998, Morse 1994, Stone 1997). We will use ATLAS.ti, a qualitative data analysis management software program to facilitate our multi-step iterative coding and analysis. First, the coders will independently read and analyze an initial batch of interview transcripts using a process of identifying salient content from narratives and developing descriptive and interpretive codes that capture the underlying meaning of the narrative content. Then, coders will meet to review their coding, and reach consensus on code names and meanings. Then, the coding team will complete coding of all transcripts through a process of independent coding followed by consensus meetings to reach agreement. The codebook will be revised and refined throughout the coding process as needed. Once all transcripts have been collaboratively coded, analytic domains will be identified and major and minor thematic areas will be described. Data from the fixed questions will be entered into a password-protected Microsoft Access® database and exported into IBM Statistics v19 (SPSS Inc., Chicago, Illinois 2010) for analysis. Descriptive statistics will be used to describe the study participants and their practices.

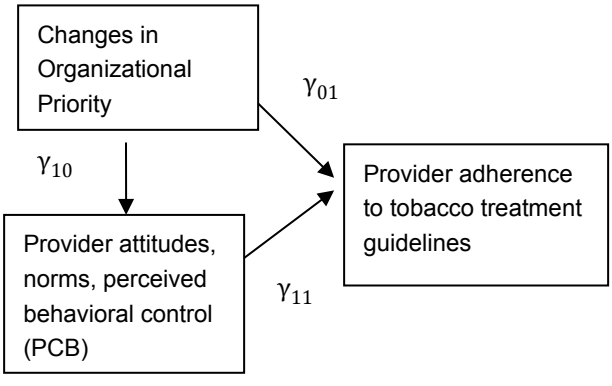
In addition, quantitative evidence will also be sought in a 2-level MLM model as follows:

Level 1: $\text{PEI}_{[j,\ k]} = \alpha_{[j,k]} + \beta_{0[j,k]} \cdot \text{Norm}_{[j,k]} + \beta_{1[j,k]} \cdot \text{PCB}_{[j,k]} + \beta_{2[j,k]} \cdot Attitudes_{[j,k]} + \varepsilon_{[j,k]},\ \ \varepsilon_{[j,k]} \approx N(0, \sigma_1^2),$

Level 2: $\alpha_{[j,k]} = \gamma_{00} + \gamma_{01}\,\mathrm{OrgChange}_j + \gamma_{02}\mathrm{Tx}_k + \gamma_{k1}, \qquad \gamma_{k1} \approx N(0, \sigma_2^2),$

$\beta_{0[j,k]} = \gamma_{10} + \gamma_{11}\mathrm{OrgChange}_j + \gamma_{12}\mathrm{Tx}_k + \gamma_{k2}, \qquad \gamma_{k2} \approx N(0, \sigma_3^2).$

Figure 2. Model for hypothesized mechanisms of action



The model posits that provider tobacco cessation assistance works through both changes in dentists' attitudes (represented by the Norm, PCB, and Attitudes covariates) and by changes in the organizational priority ($\mathrm{OrgChange}_j$).

AIM 3. To identify baseline organizational factors that influence the implementation of evidence-based tobacco use treatment practices in dental clinics. Aim 3 seeks to identify organizational characteristics (e.g., organizational change capacity and organizational structural factors) at the level of dental clinics that may help to explain variation in primary outcomes (e.g., provider cessation treatment behaviors as reported by patients the PEI (Pbert 1999) in a 2-level MLM. At level 1, provider cessation treatment behaviors will be the outcome of interest. At level-2, organizational characteristics and implementation strategy assignment will be used to explain the differences in provider assistance behaviors. It would be prudent to restrict this only to main effects because adding interaction terms risks model over-fit due to the relatively limited sample size at the provider level. As such, an additional Bayesian hierarchical model will be sought using the modeling framework of Gelman and Hill (2008) to minimize the influence of the sample size limitation, and to explicitly calculate the posterior Highest Density Regions of the main effect sizes. Generally, a Bayesian approach is suitable in understanding what components of study implementation strategies worked best when the sample size is not large (IOM 2001, Thompson 2004, West 2007).

Statistical Power and Sample Size Considerations:

We calculated statistical power to ensure sufficient sample size to address two key components of study aims. We ensured sufficient statistical power to 1) detect an omnibus effect on the primary outcome of PEI scores across three intervention conditions, against the null hypothesis that providers' assistance behaviors are equal across intervention conditions; and 2) detect the differences in provider assistance rates (e.g., quitline referral).

6. Data Storage and Confidentiality

MSKCC serves as the Data Coordinating Center for the DUET study. All survey data will be managed through REDCap (Research Electronic Data Capture), a data management software system resource hosted and supported by the Core Informatics Group of the Clinical and Translational Science Center (CTSC) of Weill Cornell Medical College (all MSKCC investigators are affiliated with this CTSC). REDCap is a widely used tool for the creation of customized, secure data management systems including web-based data entry forms, reporting tools, and a full array of security features including user and group based privileges with a full audit

trail of data manipulation and export procedures. REDCap is maintained on Weill Cornell CTSC servers that are kept in a locked server room with appropriate environmental modifications (e.g., special air conditioning), supported by an uninterrupted power supply, and backed up nightly with some backup tapes stored off-site. All connections to REDCap utilize encrypted (SSL-based) connections. The Weill Cornell CTSC IT infrastructure/environment for hosting and supporting the secure use of the REDCap software system has been reviewed and approved by MSKCC's IT Systems and the MSKCC's Privacy Office.

Each participant will be assigned a unique code number that will be used for all study records. Baseline and follow up data collected from each subject will be identifiable solely by this unique code. The list of matching dental provider names and code numbers will be maintained in a locked file cabinet in a separate location in the NYU School of Medicine at 227 East 30th Street, 7th Floor, New York, NY 10016. Dental patient locator sheets and consent forms will also be kept in this same locked cabinet.

All data collected from the chart audits for performance feedback is de-identified and aggregated to the provider and clinic level. Individual providers can only view their data and the clinic as a whole. They cannot see performance data for other providers. At study sites that necessitate a manual chart audit (the audit of performance indicators cannot be done by generating a report electronically through the EHR), the Medical Record Number (MRN) will be temporarily recorded onto a standardized chart tool, created in Excel, to perform the chart audit at each dental clinic. Upon completion of the chart audit, the NYU research staff member will de-identify MRNs using a unique formula (i.e. multiplying MRNs by the same value). De-identified data will be uploaded to REDCap and the excel sheet will be permanently deleted from the clinic's computer. Data storage, management and statistical analysis will be done on a secured PC, licensed by the Department of Psychiatry and Behavioral Sciences. Data analysis will occur in the MSKCC Department of Psychiatry and Behavioral Sciences office at 641 Lexington Avenue, 7th Floor, New York, NY 10022. All computer systems are protected from possible external access. The data collected will be used strictly for purposes stated in this IRB application and will only be available to relevant research staff at NYU and MSKCC.

Focus groups will be taped using a digital recorder. No identifying information will be included in the audiotapes. All data will be immediately downloaded to a password protected web-based data entry portal housed and created by MSK. Once transcribed and entered into a password protected Atlas database the recordings will be deleted from the files.

Data and Source Documentation. Standardized data collection tools; directions for use and sign off requirements have been generated for this study. Most data collection will occur through a web-based program that the NYU staff will be trained in how to use. In addition they will be able to print out blank data collection surveys. MSKCC will maintain the central database for data collection including the screening and study match lists.

Quality Assurance. Registration reports will be generated to monitor patient accurals and completeness of registration data. Data quality reports will be generated to assess missing data and inconsistencies. Accrual rates and extext and accuracy of evaluations and follow-up will be monitored periodically throughout the study period and potential problems will be brought to the attention of the study team for discussion and action.

Random-sample data quality and protocol compliance audits will be conducted by the study team, at a minimum of two times per year, more frequently if indicated.

Several measures are incorporated into the research methodology to ensure accurate data collection and storage. The project coordinator will review each file to ensure compliance with the approved protocol. All cases will be reviewed with regard to eligibility and exclusion criteria as well as to ensure inclusion of all approved instruments.

7. Data and Safety Monitoring. Given that participants will be consented and all of the data will be collected by NYUSoM research staff, NYUSoM will be responsible for data and safety monitoring. As a minimal risk trial, NYUSoM will conduct a DSM Review on an annual basis. Weekly registration reports will be generated by the MSKCC (Data Coordinating Center) Data Coordinator to monitor patient accruals and completeness of data forms. Routine data quality reports will be generated to assess missing data and inconsistencies. Accrual rates and extent and accuracy of evaluations and follow-up will be monitored periodically throughout the study period and potential problems will be brought to the attention of the study team for discussion and action. Random-sample data quality and protocol compliance audits will be conducted by the study team, at a minimum of two times per year, more frequently if indicated. Every effort will be made by the research study team to correct any deficits in compliance and data quality accuracy. In the unlikely event of adverse event or a serious adverse event, the study team will inform the NYUSoM IRB as soon as possible but no later than 5 calendar days.

In the unlikely event that SAEs or other study related risks occur, the protocol will be amended appropriately.

8. Risk/Benefit Assessment

8.a. Risk

Loss of confidentiality is the only potential risk to patients and providers.

8.b. Protection Against Risks

There should be minimal risks or discomfort by virtue of participating in this research study. The potential risk of participation is loss of confidentiality. However, when we collect identifying data, unique code numbers will always replace patient names in the research database. Locked file cabinets will be used to store materials with identifying information (e.g. provider and patient consent forms). Only IRB approved research members and faculty will have access to data. Patient exit interviews are anonymous and will be conducted only to monitor within site changes in the primary outcome. There will be no documents linking the patient's name or any other identifying information to the study data.

For the provider surveys, we will obtain verbal consent. We will obtain written consent of providers if it is the local site IRB's preference. No identifying information or personal health information is asked for on the provider surveys. For the post-intervention focus groups, we will be obtaining written consent from the participating providers to tape the interview with a digital recorder. However, no identifying information will be included in the audiotapes, or on the transcripts of clinician interviews. All recordings and transcriptions will be stored on a password protected computer at the Behavioral Research Methods Core Facility. Once transcribed and entered into a password protected Atlas database the recordings will be deleted from the files. Providers and staff will have the right to refuse to participate without any compromise or change to their employment or status. Also, if a participant (patient or provider) is uncomfortable during an interview situation, they may stop the interview at any time without penalty.

For the retrospective chart audits (conducted to create provider performance feedback reports), we will be collecting data documented by providers as part of regular clinic care, Thus, this study component poses no more than minimal risk to providers. Furthermore, results from performance feedback reports (if randomized to the 2nd or 3rd study arms) will not result in penalty to providers, including loss of benefits or change in employment status. The chart reviews are being conducted to assess an intervention component meant to improve the quality of tobacco use treatment, and will not intervene with patient care. The data is only to be used to provide performance feedback to clinicians and poses minimal risk to patients, as the research team will protect health information identifiers from improper use or disclosure. NYUSoM has a waiver of authorization to access patient charts at facilities where research staff must conduct the chart audit manually.

Identifiable data will not leave the clinic, and is transferred to the data coordinating center, MSKCC only through REDCap.

All computer systems are protected from possible external access by third parties. The data collected for this study will be used strictly for the purposes stated in this grant application and will only be available to relevant research staff at NYU and MSKCC. NYU and MSK IRB approval will be sought prior to any data collection involving human subjects.

9. Potential Benefits to the Subjects

All patients are expected to receive quitting advice and brief cessation counseling. Some patients may individually experience no benefit. This study will yield knowledge regarding methods for improving implementation of evidence-based guidelines for treating tobacco use among clinicians serving low-income minority populations. Overall, the benefits of understanding effective methods for helping patients stop smoking far outweigh the remote possibility of a breach of confidentiality.

Participating providers and staff may benefit from the interventions which are meant to assist them with improving the quality of tobacco use treatment in their clinics. All participating providers and staff will receive training on the PHS Tobacco use Treatment Guidelines which includes how to prescribe pharmacotherapy, how and where to refer patients for more intensive counseling and how to provide brief counseling.

10. Investigator's Qualifications & Experience

This proposal brings together a strong multi-disciplinary group of investigators from New York University College of Dentistry (NYUCD) and Memorial Sloan-Kettering Cancer Center (MSKCC) co-led by Drs. Shelley and Ostroff who have extensive prior experience implementing the proposed clinical system changes across a wide range of health care settings. The investigative team also includes Dr. Li, statistician, Dr. Bach, a healthcare policy expert, Dr. Joseph Ladapo, with expertise in cost-effectiveness research, external scientific advisors (Drs. Emmons, Albert, Solberg) and several dental consultants (Drs. Queen, Yamamato, Curro, Monopoli, Kasangra) with relevant expertise in promoting adoption of clinical guidelines for treating tobacco dependence, theories of behavior change, public health dentistry and implementation and dissemination science. All study staff is required to be trained in Human Subjects and HIPAA policies and procedures and the handling of data to ensure the confidentiality in order to obtain Institutional Review Board (IRB) approval from NYU.

11. Subject Identification, Recruitment and Consent/Assent

11.a. Method of Subject Identification and Recruitment

Prior to and approximately 9 months following each dental site's enrollment, consecutive patients will be approached during their clinic visits by trained NYU research study assistants (RSAs), to determine smoking status and to obtain consent for the exit interview. Providers and staff at each site will also be recruited for surveys and focus groups.

Recruitment and Informed Consent:

Sites: The dental field sites are all public low cost dental clinics within the NYC metro and surrounding areas. Dental directors all received an introduction letter/information sheet and expressed interest in serving as a field study site. At the beginning of the study, all clinical and support staff of each site will be invited to a group training. The PI will explain the study to the staff during the training. Staff members will be given an option to opt out if they do not want to participate. Sites must have at least 3 FTE dental providers on staff in order to be eligible to participate.

Patients: NYU study staff will be responsible for recruitment of subjects and data collection. NYU staff is required to be trained in Human Subjects and HIPAA policies and procedures and the handling of data to ensure the confidentiality in order to obtain Institutional Review Board (IRB) approval from NYU. Patients with scheduled non-emergency visits at the dental health center will be approached in the waiting room of each site and given a brief screening survey to assess current tobacco use. Patients who are current smokers will be asked to participate in anonymous patient exit interview. The patient exit interviews will be conducted after the dental visit.

Providers: Providers and staff will be told about the study at a group meeting. NYU research staff will follow-up to contact providers and staff to administer the surveys and conduct focus groups. Provider and staff surveys will be scheduled with the help of clinic administrators and will take place during work hours. Each survey will take about 5-10 minutes, and the focus group will take about an hour. The surveys are voluntary and consent is obtained from participating clinicians prior to conducting any surveys. For the post-intervention, focus groups we will be obtaining written consent from the participating providers to tape the interview with a digital recorder. However, no identifying information will be included in the audiotapes, or on the transcripts of clinician interviews.

11.b. Process of Consent

Patients Trained NYU research assistants (RA) will obtain verbal consent from patients for the patient exit interviews. Patients will be screened for current tobacco use in the waiting room of each dental clinic. Interested potential patients will give informed consent. Patients have the right to refuse to participate without any compromise of their health services.

Providers: All clinical and support staff of each site will be invited to a group training. The PI will explain the study to the staff during the training. Staff members will be given an option to opt out of the training and survey administration if they do not want to participate.

The provider surveys are voluntary and consent is obtained from participating clinicians prior to conducting any surveys. Providers will be invited to participate in the provider surveys in one of two ways: 1) through a secure link sent via email through REDCap or 2) on paper. Two survey methods are offered to accommodate providers and to increase potential participation. The consenting process differs depending on whether the survey is conducted via paper or web-based (see below).

REDCap: At the beginning of the study, the PI will ask the Dental Director if they are willing to share a list of all of their provider's professional/dental clinic assigned email addresses to distribute the survey. Dental providers will be invited to participate in the provider surveys via a secure link sent to their email address from REDCap. The email will contain an introduction to the study, the survey, and will inform the participant that all the data collected will be aggregated and summarized. If a provider is interested in learning more about the study they will be asked to click on a link contained in the email. The link will direct the provider an informed consent page on REDCap that shows a detailed explanation of the study and contains all of the elements of informed consent and uses the same language of the verbal consent script including the PI's, project director and NYUSOM IRB board phone numbers will be listed in case any provider has any questions about the consent process or the survey. The provider will be notified that by continuing past the informed consent page and answering the survey questions they are indicating that they fully acknowledge the terms outline within the consent and wish to participate in the survey. The script will explicitly state that provider email addresses will not be used for any other reasons besides contacting them to participate in the survey.

Provider email addresses will be entered in REDCap and assigned a non-identifiable study ID number. No other PHI will be collected in the provider survey nor assigned to this study ID. As mentioned above, provider email addresses will only be used for the purpose of contacting participants to complete the survey. No

personal email addresses will be used; only email addresses assigned by the provider's institution for professional communication will be used.

To contact participants, we will be using the REDCap feature, "Compose Survey Invitation", to send an email with the link to the secure survey to selected study ID numbers associated with a particular participating dental practice.

Once survey administration is complete, study staff will delete all provider email addresses from the REDCap database by deleting the variable entitled, "email", and all the data associated with that variable from the REDCap database.

If professional emails are not available, or the dental director does not know his/her provider's email, or if the dental director refuses, then survey administration will be done on paper.

Paper: If providers prefer to complete the survey on paper verbal consent will be obtained after the survey is fully explained to the participant by a member of the DUET study team using the verbal consent script.

For the post-intervention focus groups, we will be obtaining written consent from the participating providers to tape the interview with a digital recorder. However, no identifying information will be included in the audiotapes, or on the transcripts of clinician interviews.

Chart review data: We are seeking a waiver of authorization and consent. (See 11.e below)

11.c. Subject Capacity

The RA will read and explain the consent form to the subjects, making sure that they understand the content of the consent form. Specifically, we will ask them two questions. We will ask potential participants to repeat, in their own words, what they understand the purpose of the study to be and second, what their participation involves. If they cannot answer even one of those questions satisfactorily they will not be enrolled. Only subjects with the cognitive ability to consent will participate in this research.

11.d. Subject/Representative Comprehension

The informed consent process will be an ongoing dialogue between the RAs and the prospective research participants. The RA will ask the subjects if they have any concerns or questions. There will be adequate time for confirming that research participants understand the basic purpose and conduct of the study, and adequate time to answer all questions.

11.e. Waiver of Authorization and/or Consent

We have a Waiver of Authorization and Consent. The intervention is a quality improvement intervention that is aimed at providers to improve the quality of tobacco use treatment. In ARMS 2 and 3 performance feedback is a core component of this quality improvement (QI) intervention as it has been shown to improve provider adherence to tobacco use treatment guidelines (the primary outcome). In order to create the quarterly performance feedback reports we will conduct chart reviews every three months during the 9 month intervention period (total 3 chart reviews per site). The chart reviews assess if there is documentation that providers have followed guideline recommendations to screen all patients for tobacco use and offer cessation assistance to all smokers. The chart reviews are retrospective, and therefore review only data from patient visits in the previous three months. Since the chart audits are retrospective, it is not feasible to locate each patient seen during the previous quarter to obtain consent.

11.f. Costs to the Subject

The subject will incur no costs as a result of participating in the study.

11.g. Payment for Participation

Patients will receive a round trip Metrocard, valued at $5.50 upon completion of the exit interview.

Providers will receive a $10 Amazon gift card upon completion of each survey at baseline, 4.5 months and 9 months.

Participating sites that are assigned to arm 3 will receive payment based on performance as part of the intervention.

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