ABSTRACT

Smoking remains the leading cause of morbidity and mortality in the United States. The 2008 Public Health Service Guideline (PHS), *Treating Tobacco Use and Dependence* provides strong evidence that brief advice combined with assistance such as counseling and pharmacotherapy, can significantly increase quit rates. Unfortunately, provider adherence to Guideline recommendations is poor. Inadequate implementation of the Guideline in practice settings, particularly those serving ethnic minorities and other vulnerable populations, has contributed to growing disparities in smoking prevalence and tobacco-related illness. This proposal addresses this research-to-practice gap by examining the effectiveness of three practical and highly replicable strategies for implementing evidence-based guidelines for the treatment of tobacco dependence in dental public health clinics.

Dental providers have a credible and central role in providing tobacco cessation services. The majority of smokers see a dentist annually and tobacco use is a known risk factor for oral disease. Moreover, controlled trials have demonstrated the efficacy and effectiveness of dental office-based cessation interventions. Yet dental care settings remain a relatively untapped venue for the treatment of tobacco dependence. In order to integrate evidence-based tobacco cessation treatment into routine dental practice, optimal implementation processes and strategies must be identified.

We propose a 3-arm, cluster randomized controlled trial that will 1) Compare the effectiveness and cost of three promising *strategies* for *implementation* of the PHS tobacco use treatment guidelines: a) Staff training and current best practices (CBP); 2) CBP + provider performance feedback (PF) and 3) CBP + PF + provider reimbursement for delivery of tobacco cessation treatment (pay for performance) on provider adherence to recommended guidelines for tobacco use treatment; 2) Use a mixed-methods approach to examine potential theory-driven mechanisms at the organizational and provider level hypothesized to explain the comparative effectiveness of three strategies for implementation; and 3) Identify baseline organizational factors that influence the implementation of evidence-based tobacco use treatment practices in dental clinics.

The trial will be conducted in 18 public dental care clinics and information about implementation outcomes and processes will be derived from multiple data sources (patient exit interviews, provider surveys and semi-structured interviews). Guided by a conceptual framework that emphasizes provider beliefs and organizational characteristics, we will identify factors that influence the implementation process in dental clinics. The ultimate goal of the proposed research is to provide critical new knowledge to facilitate the widespread adoption, implementation, dissemination and sustained utilization of evidence-based tobacco use treatment strategies in dental practices across the U.S.

INTRODUCTION TO THE RESUBMISSION

The reviewers were enthusiastic about the strong public health significance of testing implementation strategies for promoting adherence to practice guidelines for treating tobacco dependence in dental settings, the strength of the research team, the theoretical framework and the rigorous study design/analytic plan. We have carefully considered and responded to reviewers' concerns. We outline our responses to five main issues. Substantive proposal revisions are denoted by ***bold italics***. 1) Add a cost analysis: Guided by the addition of a co-investigator with expertise in cost-effectiveness research, we have added a cost analysis (see Measures and Analysis). 2) Justify the primary outcome: *Provider adherence to clinical practice guidelines for tobacco use treatment was chosen* because the proposed implementation strategies are expected to change provider behavior. There is also strong evidence that provider (including dental providers) adherence to guideline recommended treatment can double or triple cessation outcomes. Rather than using fax referrals to the quitline, we now propose measuring provider behavior using a patient exit interview at the point of service, considered to be the optimal nonobservational method for measuring provider practice behavior. In addition, we have followed the reviewer suggestion to increase the study impact by *adding secondary (patient-level) outcomes* (see Table 3) to determine actual uptake of recommended cessation services and smoking abstinence. This will be accomplished by conducting follow-up telephone interviews with post-intervention smokers 3 months after they complete an exit interview. 3) Clarify conceptual framework: Two prior reviewers acknowledged the proposed theoretical framework as a strength. We have addressed the third reviewer's concerns about conceptual coherence by better integrating the theoretical framework with the intervention components, outcome measures and evaluation plan (see Conceptual framework section). Multiple theories of behavior change exist. Our proposal is guided by current findings in dissemination science, 4) Provide greater feasibility evidence: Dr. Shelley has recently published a pilot study that demonstrated the feasibility of implementing current best practices (arm 1) and performance feedback (arm 2) in dental public health clinics (see Preliminary Studies). 5) Provide rationale for selection of staff training, tobacco use screening, and referral systems as effective implementation strategies: These systems-level interventions are widely viewed as a necessary foundation for PHS guideline implementation and therefore considered as current best practices; however, gaps in quality of care remain and mandate innovations. Recognizing the additional needs of smokers with comorbid psychiatric or complex social histories, we will provide additional training and resource lists for referral to community-based psychosocial support services. Other issues: Provide more information about the dental field sites: We have now obtained letters of support from the dental directors of 18 public dental clinic sites (plus alternate clinic sites) providing ample evidence of the trial feasibility. We have also summarized the key field site characteristics indicating the commitment of a large dental workforce serving a large volume of low income patients (see Appendix C). All sites are using an electronic dental record system (e.g. Dentrix) enabling identification of smokers and routine collection of providers' tobacco treatment behavior. Finally, we found no instances of the same providers practicing at multiple field sites reducing prior concerns about contamination. Provide more detail about the qualitative analysis: The MSKCC Behavioral Research Methods Core Facility has extensive expertise and will be responsible for analysis of the qualitative data (see Analysis section). Understanding organizational changes: We have added more detailed explanation of the organizational assessment planned using practice-based, evaluation procedures used by Dr. Shelley in her prior work implementing tobacco use treatment guidelines in over 40 primary care settings in NYC (see Assessment Plan). Participation of AI/AN or NH/OPI persons: We have selected dental practices that serve a diverse patient population representative of New York metropolitan region. All patients, regardless of race or ethnicity, will be screened for eligibility. The target enrollment form has been revised to reflect enrollment of AN/AI and NH/OPI participants. Rationale and further specification of P4P payment in Arm 3**:** We have further justified the incentive amount and timing of payments as guided by prior work and consistent with a current demonstration project conducted by the NYC Department of Health (see Approach section). The incentive amount is also consistent with the current Medicaid/Medicare reimbursement schedule for 10 minutes of smoking cessation counseling and represents an amount that was judged meaningful by members of our dental professional advisory committee with representation of the American Dental Association and dental insurance industry (see Letters of Support). Sites will receive $20 for each patient with chart documentation of cessation assistance. List all key personnel: We have now listed all co-investigators including those with statistical (Li), cost-analysis (Lapado) and qualitative methods (Shuk) expertise. Justify timeline and waves: Practically speaking, the least costly project staffing strategy involves working with three sites concurrently thereby requiring six waves of data collection to enroll 18 sites (see Budget Justification). Justify inclusion of light smokers (<10 cigs/day): The practice guidelines are applicable for all smokers and we are attempting to meet the public health needs of a growing cohort of light smokers.

SPECIFIC AIMS

Smoking remains the leading cause of morbidity and mortality in the United States. The 2008 Public Health Service Guideline (PHS), *Treating Tobacco Use and Dependence* provides strong evidence that brief advice combined with assistance such as counseling and pharmacotherapy, can significantly increase quit rates. Unfortunately, provider adherence to Guideline recommendations is poor. Inadequate implementation of the Guideline in practice settings, particularly those serving ethnic minorities and other vulnerable populations, has contributed to growing disparities in smoking prevalence and tobacco-related illness. This proposal addresses this research-to-practice gap by examining the effectiveness of three practical and highly replicable strategies for implementing evidence-based guidelines for the treatment of tobacco dependence in dental public health clinics.

Dental providers have a credible and central role in providing tobacco cessation services. The majority of smokers see a dentist annually and tobacco use is a known risk factor for oral disease. Moreover, controlled trials have demonstrated the efficacy and effectiveness of dental office-based cessation interventions. Yet dental care settings remain a relatively untapped venue for the treatment of tobacco dependence. Dentists most often cite a lack training and reimbursement and inadequate organizational support as barriers to adherence to the Guideline. In order to integrate evidence-based tobacco cessation treatment into routine dental practice, optimal implementation processes and strategies must be identified in order to optimize the well-established impact of provider interventions on reducing tobacco-related health burdens.

Using a 3-arm cluster randomized controlled trial design, the research objective is to compare the effectiveness of three promising implementation strategies (staff training and clinical reminder systems, performance feedback and financial incentives) designed to address organizational and provider level obstacles for effective treatment of tobacco dependence. Guided by a conceptual framework that emphasizes provider beliefs and organizational characteristics, we will identify factors that influence the implementation process in dental clinics. The trial will be conducted in 18 public dental care clinics and implementation outcomes and process measures will be derived from multiple data sources (patient exit interviews, provider surveys, site observations, and semi-structured interviews)

The specific aims of this comparative effectiveness research trial are to:

1. Compare the effectiveness and cost of three promising *strategies* for *implementation* of the PHS tobacco use treatment guidelines on dental provider delivery of cessation assistance:

   I) Staff training and current best practices (CBP);

   II) CBP + provider performance feedback (PF); and

   III) CBP + PF + provider reimbursement for delivery of tobacco cessation treatment (pay-for-performance; P4P)

2. Use a mixed-methods approach to examine potential theory-driven mechanisms at the organizational and provider level hypothesized to explain the comparative effectiveness of three strategies for implementation; and

3. Identify baseline organizational factors that influence the implementation of evidence-based tobacco use treatment practices in dental clinics.

Our central hypothesis is that the benefit of these implementation strategies is additive and that instituting all three strategies (Current Best Practices (CBP), Performance Feedback (PF) and Pay for Performance (P4P)) will be superior to CBP alone and CBP+PF in increasing delivery of cessation assistance to smokers. The ultimate goal of the proposed research is to provide critical new knowledge to facilitate the widespread implementation, dissemination and sustained utilization of evidence-based tobacco use treatment strategies in dental practices across the U.S.

SIGNIFICANCE

Evidence-based approaches for the treatment of tobacco dependence exist. 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.[1] 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).[1] Adequate implementation of the PHS Guidelines would generate 1.6 million additional quitters per year and nearly 3.3 million quality life years saved.[2]

Inadequate adoption of evidence-based treatment contributes to growing disparities in tobacco related illnesses. Despite the existence of effective tobacco dependence treatments, inadequate adoption, particularly among low income and ethnic/racial minority smokers, has contributed to growing disparities in smoking prevalence and tobacco-related illness.[3-5] For instance, Hispanics are 57% and African-Americans 13% less likely to receive physician advice to quit than non-Hispanic whites.[3] ***Citing persistent missed opportunities to promote tobacco cessation, the Institute of Medicine's (IOM) report, "Ending the Tobacco Problem: A Blueprint for the Nation", calls for greater efforts to implement effective tobacco cessation interventions in health care settings. The USDHHS Task Force on Tobacco Control recently highlighted the need to better understand provider incentives and other system-level strategies to motivate provider adherence to PHS guidelines and leverage emerging opportunities for reimbursement of preventive services as presented by the 2010 Affordable Care Act. These recent health policy reports highlight the need and potential public health value of reducing tobacco-related disparities through dissemination of evidence-based interventions in health care delivery systems serving low income and other high-risk smokers.[6,7]***

Dental health care settings are an important but underutilized venue for tobacco use treatment. Dental care settings have several advantageous features for delivery of tobacco cessation treatment including: 1) broad reach with 62.8% of 18-64 years olds reporting at least one annual dental visit,[8] 2) access to patients who do not receive other healthcare services (10% of dental patients do not regularly see a physician),[9] 3) the dental team routinely provides preventive services; and 4) controlled trials have demonstrated the efficacy of dental office-based cessation interventions.[10] Moreover, dental professionals have a credible role in providing tobacco cessation treatment in view of the oral hazards of tobacco use. A recent national survey found that 88.7% of dentists and 96% of dental hygienists reported that treating tobacco use was an important professional responsibility.[11] Although most dentists still work in private practice settings, there are about 475 federally-funded, community or neighborhood health centers with dental clinics and another 250 community dental clinics throughout the United States.[12] These community dental health centers serve predominantly low income populations known to have a high prevalence of smoking.[13] Therefore, the potential impact of implementing the Tobacco Guidelines in these public health dental clinics is substantial.[10] Unfortunately, delivery of tobacco use treatment in routine dental care remains limited.[11,14,15]

Treatment of tobacco dependence in dental care settings remains suboptimal. Although 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).[11,15] Dentists most often cite lack of training, and adequate reimbursement to explain their subpar performance in providing tobacco cessation interventions.[14] Challenges to wide-scale implementation of tobacco dependence treatment also include a lack of referral resources and a lack of office-based systems.[10,14] PHS guideline implementation is likely affected by both provider attitudes and organizational priorities that impact provider behavior.[1,15-18]

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. Drawing from a burgeoning dissemination science literature, the proposed study compares the cumulative benefit of the following three systems-level strategies: 1) staff training and clinical reminders, 2)

provider feedback and 3) pay-for- performance (financial incentives), that have been widely endorsed by a 2001 Institute of Medicine Report, "Crossing the Quality Chasm" [21] and the 2008 PHS Guidelines.[1,20,21]

Staff Training and Clinical Reminder Systems. The PHS Guideline strongly recommends staff training, clinical reminder systems and other practice supports as the foundation for treating tobacco dependence in health care settings. Despite observed limitations[16,22,23] , staff training, practice supports, clinical reminder systems and referral pathways represent current best practices (CBP) for screening and treating tobacco dependence.

Performance Feedback (PF). In recent randomized trials conducted in primary medical care settings, clinical audit and feedback with regard to tobacco treatment performance have been associated with a twofold increase in cessation assistance and referral to cessation quitlines.[16,24,25] While clinical audit and feedback have been shown to increase provider adherence to tobacco use treatment guidelines in medical settings, these strategies have not yet been examined in dental practice. [1,16-20].

Pay for Performance (P4P). P4P or providing financial incentives for meeting predetermined performance goals has attracted much interest as a strategy to improving guideline implementation and the quality of care.[26,27] The recent consensus report from the 2nd European Workshop on Tobacco use Prevention and Cessation for Oral Health Professionals emphasized the importance of appropriate compensation of tobacco use treatment to provide incentive to oral health providers.[28] Several studies have demonstrated a positive association between P4P and adherence to recommended tobacco use treatment.[29-31] For instance, An et al, found that a P4P program increased referrals to statewide tobacco quitline services.[29] Electronic dental records and automated billing systems (such as the Dentrix system used by most of our participating dental clinic sites) are adding nicotine dependence diagnostic and treatment procedure codes. This health informatics trend bodes well for the sustainability of performance feedback and P4P implementation strategies.

INNOVATION. The application is innovative in four areas: 1) The focus on dental practices which have been underrepresented in studying implementation of clinical guidelines for treating tobacco dependence; 2) Targeting public dental health clinics clinical settings, a novel channel for reaching minority and low-income populations who are at greatest risk for tobacco use; 3) ***The use of a multi-level, theoretical framework for examining provider and practice-level processes for PHS guideline implementation.*** A 2010 review of implementation research found that only 10% of prior studies have postulated an explicit theoretical rationale.[32] Moreover, no previous studies of PHS Guideline implementation in dental practices have provided a theoretical rationale for their implementation strategies; and finally, 4) the proposed research is innovative because it represents a substantive departure from the status quo of didactic continuing professional education in treating tobacco dependence by implementing and evaluating enhanced systems-level strategies to improve the delivery of tobacco treatment in dental clinics. Therefore, the findings will have high impact by identifying best practices for implementing tobacco use treatment in public health dental clinics and providing key stakeholders in the field, including members of our advisory committee (see Support Letters), with the data they need to make decisions regarding implementation of effective tobacco dependence treatment guidelines.

APPROACH

Relevant expertise of research team. This proposal brings together a strong multi-disciplinary group of investigators from New York University School of Medicine (NYUSOM) 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 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. **Feasibility *is enhanced by the commitment (See letters of Support) of 18 (plus 3 alternates) dental public health clinics in the New York metropolitan region dedicated to promoting treatment of tobacco dependence (See Appendix C for list of sites and characteristics).*** The research team is uniquely positioned to carry out this high impact research.

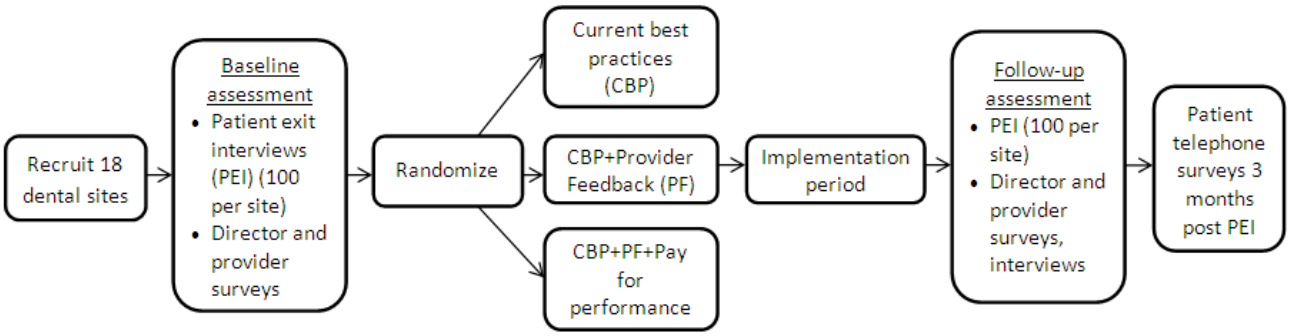
Drs. Shelley and Ostroff have considerable experience studying the implementation of tobacco use treatment guidelines in both medical and dental practices and specifically public health clinics serving low income smokers. Over the past six years, as PI of the NYS DoH-funded Manhattan Tobacco Cessation Center (MTCC), Dr. Shelley has developed and tested strategies for guideline implementation and evaluation.[23,33,34]

As part of the MTCC activities, Dr. Shelley is currently working with over 50 health care centers (including 14 dental clinics at NYUCD) in which she has implemented tobacco use treatment related system changes including chart reminders (paper and electronic) and the fax referral system linking health care centers with the State Quitline. In addition, she has trained over 300 providers to adhere to clinical practice guidelines for treating tobacco use. Dr. Ostroff has parallel experience as Co-Leader for the NYS supported QueensQuits! Tobacco Cessation Center, providing training and technical assistance in treating tobacco dependence to more than 30 health care settings in Queens County, New York. To date, most of the work of these state-funded Cessation Centers has focused on primary medical care whereas this application provides an invaluable opportunity to systematically extend this line of work to dental primary care.

Preliminary studies. ***Dr. Shelley recently published a single arm, pilot study to test the feasibility and promise of implementing Arm 2 of the current proposal (i.e., Current Best Practices (CBP) plus provider feedback) in six public dental clinics.[35] The main outcome measure—provider adherence to tobacco use treatment guidelines—was assessed by auditing a random selection of dental chart documentation pre (698) and post (641) introduction of this implementation strategy. Providers were significantly more likely to offer advice (28.4% pre, 49% post), assess readiness to quit (17.8% pre, 29.9% post), and offer assistance (6.5% pre and 15.6% post) following implementation of CBP and performance feedback.[35,36] Of note, this pilot project had insufficient resources to conduct patient exit interviews, considered a more rigorous measurement tool for assessment of provider behavior.***

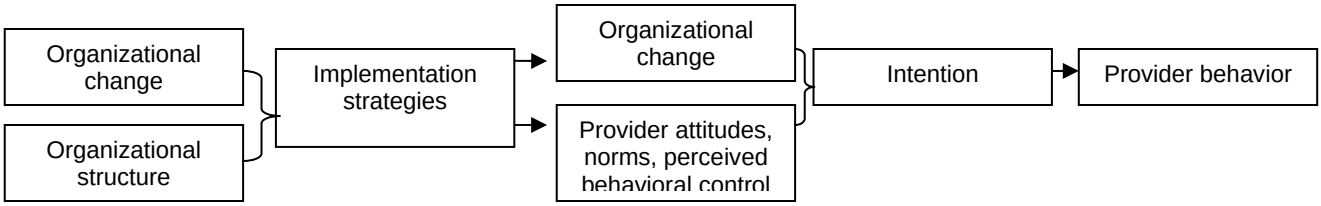
Study Design. We propose a 3-arm cluster randomized controlled trial that will analyze the implementation process and compare the ***cost and*** effectiveness of three implementation strategies: 1) Staff training and CBP in implementing PHS Guidelines; 2) CBP + provider performance feedback (PF) and 3) CBP + PF + Pay-for-performance (provider reimbursement for tobacco cessation treatment delivery). Guided by Organizational Change Theory and the Theory of Planned Behavior,[37-40] 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 found through extensive meta-analysis[1] to be an essential determinant of patient cessation outcomes. 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



Conceptual Framework. Recent reviews of the implementation literature suggest multiple levels at which interventions operate, including the individual health provider and the organizational system.[38,40-42] Our conceptual framework and corresponding selection of process measures are informed by both Solberg's Organizational Change Model for studying practice improvements[40] as well as the Theory of Planned Behavior (TPB).[37] Guided by these two theoretical models, our proposed implementation strategies are hypothesized to operate at the both the individual health provider level and the organizational level factors (See Figure 2).

Figure 2. Conceptual Framework



Solberg posits that the main organizational factors predicting implementation are organizational change capacity, and organizational priority (i.e., extent to which the organization supports implementation of tobacco use treatment guidelines relative to other priorities) and effective system changes, which in this proposal are targeted by the proposed implementation strategies. [19,38,39,43-46] ***This model posits that implementation strategies (i.e. system changes) will influence organizational priority. In addition, the implementation strategies are hypothesized to operate through changes in dental provider attitudes (i.e., the degree to which performance of the behavior is positively or negatively valued), subjective norms (i.e., perceived social pressure to engage in a behavior based on perceived social comparison with other providers) and perceived behavioral control (i.e., perceptions of their ability to perform a given behavior) all constructs from the Theory of Planned Behavior (TPB).(see Table 2 below).*** [47-49,37] ***TPB is a robust theoretical model that has been applied successfully to explain clinical behavior change among health care providers.*** [22,50-53] ***A recent synthesis of studies using social cognitive theories of behavior change found that the TPB model has been the most commonly used theory to predict clinical behavior of health professionals and explained 31% of the variance in provider behavior.*** [50]

Table 2 Theory-driven mechanisms hypothesized to explain the effect of the implementation strategies.

Table 2. Implementation Strategy	***Theory-Driven Hypothesized Mechanism(s) of Change***
ARM 1 Staff training and current best practices (CBP)	Increases perceived behavioral control
ARM 2 CBP + audit and performance feedback (CBP+PF)	Increases perceived behavioral control AND modifies subjective norms and attitudes
ARM 3 CBP + PF + pay for performance (CBP+PF+P4P)	Increases perceived behavioral control, provider attitudes AND increases organizational change priority

ARM 1 (e.g., provider training, chart reminders, practice support for referral to the Quitline or other local programs) is hypothesized to impact perceived behavioral control (i.e. self efficacy). We hypothesize that the addition of provider feedback, (ARM 2) will result in enhanced provider adherence to the tobacco use treatment guidelines through changes in subjective norms and attitudes. ARM 3, which adds financial incentives, addresses a frequently cited organizational barrier (i.e. lack of reimbursement). We hypothesize that financial incentives will impact the relative priority that organizations and providers attribute to tobacco use treatment.

Intervention Conditions. Specific implementation strategy components:

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. Smokers' chart audit and quarterly Performance Feedback reports		X	X
6. 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 onsite 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 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 1.5-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 Fax-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.[1] The proposed protocol, including the provision of pharmacotherapy is consistent with American Dental Association (ADA) recommendations.[54] 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.[13,23,55] Trainings will be conducted by Dr. Shelley and her MTCC staff and offered onsite at each individual field site. Consistent with well-established treatment fidelity recommendations for ensuring adequate training of treatment providers [56] we will standardize initial provider training and evaluate the adequacy of training by measuring provider skill acquisition post-training through the observation of role play of hypothetical case vignettes.
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 (See Appendix A.1 for example of electronic chart system) 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). ***All of the partnering dental health clinics are currently using the Dentrix System, a dental practice and clinical management software tool. 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. **Fax to Quit Referral System:** Quitlines substantially increase abstinence rates compared to minimal or no counseling.[1] New York State (NYS) began operating a smokers' Quitline in 2000 and receives over 35,000 calls per year.[1] The "Fax-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 (Appendix A.2). 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. **We will also provide a list of community referrals for high risk smokers needing more intensive cessation and/or psychosocial services.**
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 (Appendix A.3.), a laminated pharmacotherapy prescribing information card tailored for dental providers (Appendix A.4), Fax-to-quit forms, and the brief version of the PHS guideline for Treating Tobacco Dependence.[1]

ARM 2: CBP + audit and performance feedback

Chart Audit and Quarterly Feedback Reports: Field sites randomly assigned to Arm 2 will receive quarterly performance reports on provider delivery of cessation services using chart audit procedures that we have used successfully in prior work. ***All of the study sites have an electronic record system which will capture tobacco use and allow sites to create a registry of patients who are tobacco users. We will conduct quarterly queries of the registry, and*** **consistent with routine practices followed by the Manhattan Cessation Center, trained clinic staff will use a standardized chart audit tool (Appendix A.5) to *evaluate documentation of cessation assistance.*** Feedback reports and recommended practice goals will be based on an "Achievable Benchmark of Care" which is the approach used by Bentz and Wadland.[24,25] and will be delineated in a policy document (Appendix A.6). The feedback report (Appendix A.7) will show individual and clinic performance summaries of two targeted provider behaviors based on documentation in the chart: 1)

percentage of smokers advised to quit, and 2) percentage of smokers who received quitting assistance. Quitting assistance will be fulfilled by documentation of any of the following provider behaviors: a) Faxing a referral to the NYS Quitline, b) Chart documentation of providing cessation counseling; and/or c) discussing and or prescribing cessation medications..[24,57] Reports will be given to the Dental Director, who will be instructed to distribute them to dental providers no later than 30 days following the end of the quarter.

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[58,59] 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 (Drs. Monopoli and Yamamoto) (See letters of support).

Field Sites: Eligibility and recruitment: Selection of performance sites is guided by our desire to insure that our findings would be generalizable to real-world dental health care settings serving diverse population of smokers. We will partner with 18 public health dental clinics that have expressed willingness to participate (See letters of support from field sites) (Appendix C provides a table of the characteristics of these sites). For practical (cost and staffing) reasons, we will recruit sites in six successive waves with three sites enrolled per wave (see Timeline). Site randomization will be conducted by the MSKCC Clinical Research Database Program (CRDB) within the Biostatistics Service using the random permuted block method.

Assessment Plan. Our assessment plan is intended to compare the effectiveness of three *strategies* for *implementation* of the tobacco use treatment guidelines, to examine multi-level, theory-driven mechanisms (organizational, provider beliefs) hypothesized to explain the effectiveness of the three strategies for implementation, and finally to identify multi-level barriers and facilitators that that may influence the implementation of evidence-based tobacco use treatment practices in dental clinics. Mixed methods (i.e., observational, interview and survey) data will be collected from patients, providers, dental directors, dental charts and Quitline use surveillance data. For clarity, our assessment plan is organized according to following evaluation domains: Primary Outcomes, Secondary Outcomes, Process Outcomes, Organizational Characteristics, and Implementation Fidelity.

Table 3. Evaluation data sources in relation to specific aims:

	Data Source	Instrument	Administration	Variables	Specific Aims
Primary Outcome	Patients	Patient Exit Interviews (PEI)[33]	Baseline, 12 month following site enrollment	Provider adherence to tobacco use treatment guidelines	1
	Costs	Cost collection template (see Appendix B.3)	Ongoing	Research and clinical intervention costs	1
Secondary Outcomes	Patients	Telephone Survey (see appendix)	3 months post-PEI	• Utilization of tobacco treatment services • Smoking abstinence (7 day point prevalence)	1

Process Outcomes	Dental Providers	Goldstein and Francis/Grimshaw measure[35, 50] Semi structured Interviews	Baseline, 6 and 12 month following site enrollment Baseline and 12 months	• Provider attributes, norms, perceived behavioral control and intention regarding treating tobacco use • Perceived organizational change priority[59] • Perceived barriers and facilitators • Satisfaction and acceptability of the implementation strategies	2
	Dental Directors	Survey Semi structured interviews	Baseline, 6 and 12 months Baseline and 12 months	• Organizational change priority[60] • Perceived barriers and facilitators • Satisfaction and acceptability of the implementation strategies	2
Organizational Characteristics	Dental Directors	Change Process Capability Questionnaire (CPCQ)[60]	Baseline	Change history, refinement plans, change capacity	3
		Organizational Structure	Baseline	Dental staff FTE, payor mix, academic affiliation/ownership, staff characteristics [59, 61,62]	3
Implementation Fidelity	Dental Directors	Implementation Fidelity Survey	3, 6, and 12 months following site enrollment	Documentation of implementation strategy delivery	1
	Site observations	Site assessment tool (Appendix B.8)	3, 6 and 12 months following site enrollment	Pre and post intervention chart and referral systems, workflow	1
	Dental Chart	Chart audit form (Appendix A.5)	Baseline and quarterly during intervention period	Documentation of adherence to tobacco use treatment guidelines (the 5As)	1
	NYS Quitline	Quitline reports	Baseline and Quarterly	Confirmation of changes in Quitline referral patterns	1

Outcome Evaluation (Aim 1) *Primary outcome:* To assess the primary outcome of provider adherence to tobacco use treatment guidelines, we will conduct patient exit interviews with 100 smokers pre and post-intervention at each of the 18 study sites (1800 smokers pre and post). ***Patient questionnaires conducted at the point of service are considered to be the optimal nonobservational method for measuring provider delivery of outpatient treatment.[61,62] The Patient Exit Interview (PEI)[63] is a brief patient-reported measurement tool for the assessment of provider delivery of tobacco use treatment. A PEI index (summary) score is determined by adding the number of intervention steps each patient reports that the physician implemented. PEI index scores range from 0 (no steps used) to 10 (all steps used) (Appendix B.1). The questions assess the full spectrum of PHS guideline recommended care (i.e., 5As). For example, patients are asked if their provider advised them to quit, offered cessation counseling and/or discussed cessation medications. It has well-established validity as evidenced by strong correlation with more costly audiotaped assessment of physician-patient interactions ($r = .67$, $p < .001$) and has been commonly used to accurately measure providers' delivery of tobacco cessation assistance efforts during office practice, and to monitor providers' adherence to tobacco cessation treatment guidelines in clinical trials.*** Prior to and approximately 12 months following each site's enrollment, consecutive patients will be approached during their clinic visits by trained research study assistants (RSAs), to determine smoking status and to obtain consent for the exit interview. Patient eligibility includes: 1) age 18 or over; and 2) active smokers defined as those who report smoking within the past 7 days. Immediately after their dental visit, patients will complete the PEI to assess provider adherence to the PHS Guideline (5As).

Cost analysis: Following recommendations for cost assessment methodology described by Ritzwoller et al.,[64] we will separate estimate research costs (e.g. labor and other inputs associated with grant administration, IRB approval, manuscript prep) and direct clinical intervention costs (e.g. dental provider time associated with counseling patients, staff training, IT costs, reimbursement costs). We will develop templates (see Appendix B.3 for example of cost data collection tool) to capture data prospectively to improve accuracy and precision of cost assessment. The NYS Quitline has estimates

of their counseling cost per quit. We will also estimate the costs of the medications taken by the patients as part of their cessation attempt (reported at the 3 month telephone survey).

***Secondary outcomes:* To assess patient utilization of cessation services and smoking abstinence, we will conduct follow-up telephone interviews, three months post clinic visit, with smokers who complete the post intervention PEIs. We will use a standardized interview that we have used successfully to collect patient-reported outcomes in our prior cessation research (see Appendix B.2).**

Implementation Process Evaluation (Aim 2)

The process evaluation encompasses three areas: 1) Theory of Planned Behavior (TPB) processes; 2) Solberg's construct of Organizational change priority; and 3) Acceptability of and satisfaction with the implementation strategies. The data sources (see Table 3) include: (1) surveys with participating dentists and dental directors; and (2) semi-structured interviews with dental clinic directors, dentists and staff.

Dental Director and Provider surveys: Measures for the four TPB variables (attitudes, subjective norms, perceived behavioral control and intentions) are based on selected subscales from established survey tools (Appendix B.4). We will use Park and Goldstein's scale (Cronbach alpha 0.83-.86) to assess attitudes and self efficacy[65] and will draw from Francis and Grimshaw's tool to assess norms, perceived behavioral control and intention.[51,53] We will supplement Solberg's measure of organizational priority by adapting a 7-item scale validated in previous work with reliabilities ranging from 0.87 to 0.93 (Appendix B.5).[43]

Semi-structured interviews will be conducted with all participating dental providers, dental directors and other key informants, including stakeholders in administrative and technical roles before and after the intervention. The interviews will be informed by the TPB and also 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).

Baseline Organizational Characteristics (Aim 3)

Organizational change capacity: We will use the Change Process Capability Questionnaire (CPCQ) (Appendix B.6) to assess baseline measures of organizational capacity to change.[55] Several tools are available to test organizational readiness and capacity; however Solberg and colleagues have developed a tool that is specifically applicable to primary care practice. In a study examining improving the quality of depression care, the CPCQ was highly correlated with organizational priority for depression improvement as well as with the presence of overall systems for depression care.[55] The survey is divided into three domains that correspond to the three domains of the Ingersoll definition of capacity to manage change: history of change (3 items), plans for continuous organizational refinement (3 items), and ability to initiate and sustain change (10 items)

Organizational Structure: At baseline, we will collect data on setting level variables shown to influence implementation of provider practice guidelines including number of full-time equivalent staff, insurance payor mix, hospital based or free standing clinic, academic affiliation, clinic volume, and staff characteristics.[66,67-70] We will also conduct dental director surveys in order to identify pre-intervention clinical systems and policies (e.g. electronic or paper chart system) (Appendix B.7).

Implementation Fidelity. We will use several approaches to measure fidelity of the 3 implementation strategies.

Current Best Practices. At baseline, we will conduct onsite observations (see Appendix B.8) to assess clinical processes and workflow (e.g., patient registration, how referrals are handled, who currently screens patients for tobacco use) and we will repeat these site observations at 3, 6 and 12 months following site enrollment. During these site visits, we will confirm that use of the dental chart system and Fax-to-Quit forms are being executed as recommended. ***We will use state quitline data as an additional source of information to confirm increases in referral rates in the post intervention period. The NYS Quitline provides monthly reports to the Cessation Centers that include the number of fax referral forms received by site and provider.*** In addition, we will record the percentage of staff who attend the CBP training.

Chart Audits and Performance Feedback. As an additional fidelity measure, the Dental directors will be queried at 3,6 and 12 months to confirm date of distribution of the quarterly performance feedback reports and the dental providers will complete a survey assessing whether they received performance feedback reports, as well as their satisfaction with the reports.

Pay for Performance. The dental directors assigned to P4P will be asked at 3, 6, and 12 months to confirm receipt of the quarterly financial incentive earmarked to performance of tobacco treatment interventions.

Statistical Considerations and Analytic Plan

General Approach: The study plans to recruit 18 sites and randomly assign them into three implementation strategies (interventions) in a multiple-level, cluster-randomized design. The general statistical paradigm for assessing outcomes will be based on a Multi-Level Model (MLM) approach[71] (also known as "hierarchical linear model"). [9,30,72,73] 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), 100 patients per site will be assessed through standardized Patient Exit Interviews to establish the baseline level of dental provider assistance in tobacco cessation. Then the sites enter their assigned intervention conditions. ***Post intervention we will again recruit 100 patients for assessment of changes in provider adherence to tobacco treatment delivery guidelines.***

Implementation Fidelity. Using the indicators described in the evaluation plan (See Table 3), 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.[74]

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: $PEI_{k[i,j]} = \alpha_{k[i,j]} + \beta_{0k[i,j]} \cdot [post - pre] + \boldsymbol{\beta} \cdot \mathbb{X}_{k[i,j]} + \varepsilon_{k[i,j]},\ \varepsilon_{k[i,j]} \approx N(0, \sigma_1^2),$

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 $\boldsymbol{\beta} \cdot \mathbb{X}_{k[i,j]}$ term. [72,73,75] 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:
$$\alpha_{k[i,j]} = \gamma_{00} + \gamma_{01} Tx_k + \gamma_{k1}, \qquad \gamma_{k1} \approx N(0, \sigma_2^2),$$
$$\beta_{0k[i,j]} = \gamma_{01} + \gamma_{11} Tx_k + \gamma_{k2}, \qquad \gamma_{k2} \approx N(0, \sigma_3^2).$$

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 (100 per site) will be assessed 3 months after the exit interviews, as part of the 3 month follow up surveys 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: $Pr(abstinent)_{k[i,j]} = log^{-1}\left[\alpha_{k[i,j]} + \boldsymbol{\beta} \cdot \mathbb{X}_{k[i,j]} + \varepsilon_{k[i,j]}\right],\ \varepsilon_{k[i,j]} \approx N(0, \sigma_1^2),$

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

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 $\left[\boldsymbol{\beta} \cdot \mathbb{X}_{k[i,j]}\right]$ ***) 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.***

<u>Cost analysis.</u> 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. Base case analyses outcomes will be expressed both using the outcome in terms of cost per life year; however, in sensitivity analyses, we will also assess the outcome of cost per quality-adjusted life year (QALY) and cost per life year.[76] Using cessation outcomes from the three month post PEI telephone surveys, we will develop a predictive model of expected health and cost outcomes associated with smoking cessation.[77,78] 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 semi-structured interviews of the dental directors and providers will be transcribed verbatim by an outside transcription vendor (RL Fisher). Led by the experienced Qualitative Methods Specialist (See Biosketch, 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.[79-81] 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.

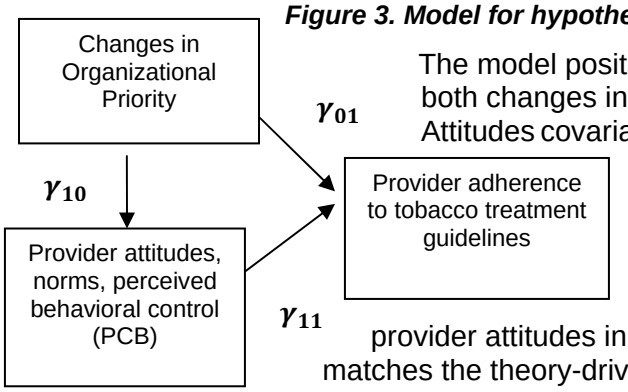
In addition, quantitative evidence will also be sought in a 2-level MLM model as follows:

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

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 3. 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 ($\mathrm{OrgChange}_j$). Of particularly importance is the γ_{11} parameter, which tests whether or not there is an interaction between providers' attitudes and the perceived organizational change priority. A synergistic interaction is plausible, in that higher levels of organizational priority may boost the influence of provider attitudes in tobacco cessation assistance. Furthermore, this MLM model matches the theory-driven mechanisms depicted in the diagram below. The implementation strategies may work through solely changes in organizational priority (testable by γ_{11}) and/or by changes in provider attitudes (testable by γ_{00}). A synergistic interaction of the two is testable by the indirect pathway of organization priority through changes in provider attitudes, which is manifested by both γ_{11} and γ_{10}). The model above only includes one covariate at each level to make the notations more trackable.

Using the CBP intervention (Arm 1) as the reference, Performance Feedback is most likely to operate through changes in provider attitudes or subjective norms whereas the Pay for Performance intervention is mostly likely to operate through increased organizational change priority. The difference in provider assistance between Provider Feedback and Pay for Performance interventions may be observed through an interaction term between treatment group contrast (CBP+PF+P4P vs CBP+PF) and increased organizational priority.

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 [82]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 [29] 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. [21,83,84]

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).

For the primary outcome of provider assistance behaviors as assessed by the PEI, we obtained prior data from a recent clinical trial conducted to improve treatment of tobacco dependence in primary care.[85,86] The investigators compared Intervention (a provider training program similar to but less comprehensive than our Performance Feedback condition) with Usual Care. The Intervention group reported an average PEI provider assistance score of 8.40 (sd=1.93) vs. an average of 6.24 (sd=2.12) in the Usual Care group, which translates to an estimated effect size of 1.02 (using the larger sd=2.12). Using this 1.02 effect size as the prior data, we estimated an 86% statistical power to detect such an effect at a two-sided Type-I error rate of 0.01 (thus to control for multiple comparisons) for 18 sites (6 sites randomized to each intervention condition) and 100 post-intervention patients per site.[87]

We also estimated statistical power for specific provider assistance behaviors in a GEE approach to the proposed MLMs. Bentz et al. reported that 10.5% of providers randomized to the Control condition gave active assistance (e.g., referrals to quitlines); and 20.1% of providers randomized to their Feedback condition gave active assistance. Roski et al. [31] reported a 31.4% cessation assistance rate for sites randomized to the Pay for Performance condition. Hence we estimated that the provider assistance rates in our study will be 10%, 20%, and 30% (rounded to the nearest 2nd decimal point) for our CBP, CBP+PF, and CBP+PF+P4P arms, respectively. Horton's simulation method [88] was applied to calculate the statistical power of a logistic GEE model. The simulated statistical power was 82% statistical power to detect a 20% vs. 10% difference in a GEE model comparing CBP+PF vs CBP alone. The corresponding statistical power for the 30% vs. 20% difference between CBP+PF+P4P and CBP+PF is 73%. The statistical power for the larger 30% vs. 10% difference between CBP+PF+P4P and CBP alone is 97%. Other parameters in the simulations included a two-sided Type-I error rate of 0.01 to control for multiple comparisons and an intra-class correlation of 0.22, as reported in Bentz et al.[89] which closely resembles our trial design.

Strengths and limitations: The study builds upon prior research and provides practical, multi-level strategies to optimize the implementation of tobacco dependence treatment in dental settings. This project is highly feasible and has numerous scientific strengths. Significant efficiencies are evident, as the grant leverages Dr. Shelley's leadership of the Manhattan Cessation Center and Dr. Ostroff's co-leadership of the QueensQuits! Cessation Center, parallel demonstration projects funded by the New York State Department of Health that provide a unique infrastructure for field site recruitment. This trial will leverage these pre-existing resources and provide an invaluable opportunity to expand the scope of scientific work, thereby accelerating the tempo of scientific discovery and dissemination of evidence-based strategies for treating tobacco dependence.

Careful consideration was given to potential methodological challenges that may be encountered during the proposed project. First, in order to assure adequate power for achieving the primary aim, we will need to recruit 18 public dental health centers. We have obtained letters of support from 18 dental directors (plus 3 alternates) who have expressed enthusiasm for trial participation. We have also obtained letters of support from several prominent gatekeepers who have pledged their commitment to recruiting adequate number of community-based dental practices. Second, it is possible that we will observe variation in implementation fidelity. Based on our collective expertise in provider training and clinic-based system changes to improve tobacco use treatment, we will standardize our training and technical assistance procedures. In addition, we will measure non adherence to the implementation strategies and include this variable in our analyses. ***Third, we have defined the core elements of the intervention arms, however, based on our previous experience and review of the current implementation literature, we acknowledge that adaptations to the unique practice context will be necessary. We will use our baseline qualitative and quantitative assessment to tailor the specific intervention components to achieve the best fit. We also have a strong implementation fidelity measurement plan to assess whether core implementation elements are achieved; however, we will also document adaptations to enhance external validity).*** Finally, unforeseen changes in tobacco policy may affect implementation outcomes (e.g. tobacco tax, changes in Medicaid reimbursement). Our plan to collect data on provider cessation behavior from each site prior to enrollment will allow each site to serve as their own control and thereby allow us to analyze for any historical threats to internal validity.

Sustainability. We have chosen to evaluate implementation strategies that are likely to be replicable and sustainable. The system changes (e.g. reminders, documentation, referral pathways, etc), tailored to the context of each site, will ensure that tobacco use screening and treatment is integrated into routine care. We will also be building capacity among dental clinic staff, through training and ongoing assistance, to conduct audits of the electronic and paper chart records and to develop performance feedback systems that can be applied to future quality improvement projects. We will also work with sites randomized to Arm 1, after the trial is completed, to provide additional training regarding conducting performance feedback.

Timeline. We will recruit sites in six waves with three sites per wave (See budget justification for details).

PROTECTION OF HUMAN SUBJECTS

Human Subjects Involvement and Characteristics: Human subjects are involved in this research as survey respondents and as recipients of services from their clinician. We will follow recommendation made for the responsible conduct and protection of human subjects in cluster randomized trials. (Taljaard 2011, Weijer 2011)

Study subjects are patients of the participating community health centers. All patients with regularly scheduled visits at the health center will be screened to establish smoking status. Study subjects will be consenting men and women age 18 and over who are current smokers, and have an appointment with a dentist or hygienist for routine non-emergent care. Beyond these eligibility criteria, no exclusions will be made based on sex, ethnicity or race. We anticipate obtaining consent and conducting exit interviews with a total of 3600 patients, 1800 at baseline and 1800 post-intervention. We will also conduct 3 month follow up telephone interviews with patients who completed the post intervention exit interviews to assess use of cessation resources and abstinence. Finally, we will conduct interviews with providers and staff at the 18 participating study sites.

Sources of Research Material

Patient source materials include two cross-sectional surveys. The two cross-sectional surveys will be administered in person at the clinic and will last 10 minutes. In order to assess the use of guideline recommended care and abstinence rates we will conduct 3 month follow up telephone surveys with patients who completed the post intervention exit interviews.

Provider and staff source materials include baseline, 3, 6, and 12 month surveys and a baseline and 12 month semi structured interview.

We will also obtain de identified data from chart reviews conducted by clinic staff. Staff will be given a chart audit tool and trained to record data on documented adherence to guideline recommended tobacco use treatment (e.g., whether it is documented that patient was screened for tobacco use). The data will not contain any patient health information and will be presented in an aggregated format.

Additionally, 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. The reports do not contain any patient information.

Potential Risks and Protection Against Risk

Loss of confidentiality is the greatest potential risk to patients and providers. All data entered into the research database will be protected by confidential entry codes. For the first (preintervention) exit interviews will be applying to IRB to obtain verbal consent as this is a minimal risk study and patients will only be completing one brief survey. Therefore there will be no documents linking the patient's name or any other identifying information to the study data. For the second cross sectional post intervention exit interviews, we will need to obtain patient identifying information in order to be able to conduct the 3 month follow up telephone survey. Therefore we will obtain written consent to conduct these follow up calls. Patients will have the right to refuse to participate without any compromise of their health services.

In terms of the provider and staff interviews and surveys, we will obtain written consent to participate. However, no identifying information is included on the transcripts of clinician interviews or surveys. The interviews will be taped using a digital recorder. No identifying information will be included in the audiotapes. All interviews will be stored on a password protected computer at the Behavioral Research Methods Core Facility (see MSKCC budget justification). 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 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.

When we are collect identifying data, unique identifiers always replace patient names in the research database. Locked file cabinets will be used to store materials with identifying information (e.g., provider consent forms). All computer systems are protected from possible external access. No Internet access is possible with the research systems. 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. IRB approval will be sought prior to any data collection involving human subjects.

Adequacy of Protection Again Risk

Recruitment and Informed Consent: Study staff will be responsible for recruitment of subjects and data collection. 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 regularly scheduled visits at the dental health center will be screened by onsite research staff to establish smoking status. Patients who meet the eligibility criteria will be asked to participate in the study. Respondents who agree to participate in the pre intervention cross sectional patient survey will be asked to for verbal consent. Those that agree to participate in the second (post-intervention) cross-sectional patient survey will be asked to provide written consent to be contacted for a three month follow up survey.

Providers and staff will be told about the study at a group meeting. Research staff will follow-up to contact providers and staff to make appointments for interviews and to administer the survey. Provider and staff interviews will be scheduled with the help of clinic administrators and will take place during work hours. Surveys will take about 10 minutes and the interviews about 30-40 minutes. The interviews are voluntary and written consent is obtained from participating clinicians prior to conducting any surveys.

Potential Benefits of the Proposed Research to Human Subjects and Others

Patients in the intervention clinics will have the benefit of augmented smoking cessation services, including telephone counseling. Some patients may individually experience no benefit. This study will yield knowledge regarding methods for increasing adherence to 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.

Importance of knowledge to be Gained

Despite the existence of effective tobacco dependence treatments, cigarette smoking remains the leading cause of morbidity and mortality in the United States. Inadequate implementation of evidence-based tobacco use treatment interventions in practice settings, particularly those serving ethnic minorities and other vulnerable populations, has contributed to growing disparities in smoking prevalence and tobacco-related illness. The proposed research addresses this research-to-practice gap by examining the effectiveness of three implementation strategies that have promise to improve the delivery of clinical practice guidelines for treatment of tobacco dependence in dental public health clinics

Data safety and monitoring plan

The Data and Safety Monitoring (DSM) Plans at MSKCC was approved by the National Cancer Institute in September, 2001. The DSM is administered institution-wide by the Office of Clinical Research, including the Data and Safety Monitoring Committee (DSMC) for Phase-I and Phase-II clinical trials and the Data and Safety Monitoring Board (DSMB) for Phase-III clinical trials. In addition, there are departmental procedures in place for quality control and safety monitoring appropriate for behavioral research which typically entails low risk. Studies similar to the one propose herein may be monitored by DSMB, IRB, and other institutional/departmental monitoring committees, in accordance with the latest NIH guidelines on data safety and monitoring of clinical trials posted online on 04/27/2000 (http://cancertrials.nci.nih.gov/clinicaltrials/conducting/dsm-guidelines/page2).

This intervention represents no greater than minimal risk to the research participants. The review committees at both institutions will report any issues and/or problems identified through their review process, to the Chairman of the Center's IRB. The study will be reviewed by the committee members, in conjunction with standardized data summary reports generated for each study for MSKCC's Clinical Research Data Base to monitor patient accruals, treatment, outcomes, toxicities (if any), and adverse events (if any).

Baseline and follow-up data will be collected via computer-assisted survey interview (CASI) software by the research assistants under the direction of Dr. Shelley at the NYUSOM. Access to this data will be password-protected and housed on secure NYUSOM servers. As data management and statistical analysis will be conducted at MSKCC, data will be extracted from the CASI system on a weekly basis via upload of a delimited

file to a secure FTP server housed at MSKCC. The MSKCC Data Coordinator (Ms. Manna) will import that data into our research database.

All participants will receive a unique numerical study identifier (ID#), with no relationship to personally identifying information. If a participant withdraws they and all their data will be erased from this and all databases

The Principal Investigators will regularly monitor interviewers' work over the course of the study and will meet weekly with research staff for quality assurance and monitoring purposes, and to review problems or concerns that may arise.

Taljaard M, McRae AD, Weijer C, Bennett C, Dixon S, Taleban J, Skea Z, Eccles MP, Brehaut JC, Donner A, Saginur R, Boruch RF, Grimshaw JM.Inadequate reporting of research ethics review and informed consent in cluster randomised trials: review of random sample of published trials.,BMJ. 2011 May 11;342:2496.

Weijer C, Grimshaw JM, Taljaard M, Binik A, Boruch R, Brehaut JC, Donner A, Eccles MP, Gallo A, McRae AD, Saginur R, Zwarenstein M. Ethical issues posed by cluster randomized trials in health research. Trials. 2011 Apr 20;12:100

Inclusion of Women and Minorities. All women ages 18 and over who meet additional eligibility criteria and who agree to participate will be included in the study. There are no specific outreach programs for recruiting women into the study as all female patients meeting eligibility criteria at participating sites will be invited to participate.

All minorities ages 18 and over who meet the eligibility criteria and who agree to participate will be included in the study. This proposal does not include additional outreach programs for recruiting minorities into the study because the patient population targeted for recruitment currently consists primarily of minority patients and the study is, in fact, designed specifically to study smoking cessation among minority populations served by Dental Community Health Centers.

Inclusion of Children. The research plan proposes to test the impact of three strategies to implement tobacco use treatment guidelines in dental practices treating adult patients. The interventions are based on the Public Health Services Guideline Treating Tobacco use and Dependence which includes recommendations for adults 18 and over.

REFERENCES

1. Fiore M, United States. Tobacco Use and Dependence Guideline Panel. *Treating tobacco use and dependence : 2008 update*. 2008 update ed. Rockville, Md.: U.S. Dept. of Health and Human Services, Public Health Service; 2008.
2. USDHHS. Population based Smoking Cessation: Proceedings of a COnference on What Works to Influence Cessation in the General Population. *National Cancer Institute Monograph.* 2000;12.
3. Lopez-Quintero C, Crum RM, Neumark YD. Racial/ethnic disparities in report of physician-provided smoking cessation advice: analysis of the 2000 National Health Interview Survey. *Am J Public Health.* Dec 2006;96(12):2235-2239.
4. Fagan P, Moolchan ET, Lawrence D, Fernander A, Ponder PK. Identifying health disparities across the tobacco continuum. *Addiction.* Oct 2007;102 Suppl 2:5-29.
5. Vital signs: current cigarette smoking among adults aged >or=18 years --- United States, 2009. *MMWR Morb Mortal Wkly Rep.* Sep 10 2010;59(35):1135-1140.
6. Medicine. Io. Ending the Tobacco Problem: A Blueprint for the Nation Washington: National Academies Press; 2007.
7. Services USDoHaH. Ending the Tobacco Epidemic: A Tobacco Control Strategic Action Plan for the U.S. Department of Health and Human Services In: Health OotASf, ed. Washington, DCNovember 2010.
8. Manski RJ, Cooper PF. Dental care use: does dental insurance truly make a difference in the US? *Community Dent Health.* Dec 2007;24(4):205-212.
9. Strauss SM, Alfano, M. C., Shelley, D., Fulmer, T. Identifying Unaddressed Systemic Health Conditions at Dental Visits: Patients Who Visited Dentists but Not General Health Care Providers in 2006. *JADA* 2010;submitted.
10. Gordon JS, Lichtenstein E, Severson HH, Andrews JA. Tobacco cessation in dental settings: research findings and future directions. *Drug Alcohol Rev.* Jan 2006;25(1):27-37.
11. Tong EK, Strouse R, Hall J, Kovac M, Schroeder SA. National survey of U.S. health professionals' smoking prevalence, cessation practices, and beliefs. *Nicotine Tob Res.* Jul 2010;12(7):724-733.
12. Gordon JS, Andrews JA, Lichtenstein E, Severson HH. The impact of a brief tobacco-use cessation intervention in public health dental clinics. *J Am Dent Assoc.* Feb 2005;136(2):179-186; quiz 230-171.
13. Gordon JS, Andrews JA, Albert DA, Crews KM, Payne TJ, Severson HH. Tobacco cessation via public dental clinics: results of a randomized trial. *Am J Public Health.* Jul 2010;100(7):1307-1312.
14. Albert DA, Severson H, Gordon J, Ward A, Andrews J, Sadowsky D. Tobacco attitudes, practices, and behaviors: a survey of dentists participating in managed care. *Nicotine Tob Res.* Apr 2005;7 Suppl 1:S9-18.
15. Albert D, Ward A, Ahluwalia K, Sadowsky D. Addressing tobacco in managed care: a survey of dentists' knowledge, attitudes, and behaviors. *Am J Public Health.* Jun 2002;92(6):997-1001.
16. Curry SJ, Keller PA, Orleans CT, Fiore MC. The role of health care systems in increased tobacco cessation. *Annual review of public health.* 2008;29:411-428.
17. Grimshaw J, Eccles M, Thomas R, et al. Toward evidence-based quality improvement. Evidence (and its limitations) of the effectiveness of guideline dissemination and implementation strategies 1966-1998. *J Gen Intern Med.* Feb 2006;21 Suppl 2:S14-20.
18. Curry SJ. Organizational interventions to encourage guideline implementation. *Chest.* Aug 2000;118(2 Suppl):40S-46S.
19. Solberg LI, Brekke ML, Fazio CJ, et al. Lessons from experienced guideline implementers: attend to many factors and use multiple strategies. *Jt Comm J Qual Improv.* Apr 2000;26(4):171-188.
20. Fiore MC, Keller PA, Curry SJ. Health system changes to facilitate the delivery of tobacco-dependence treatment. *Am J Prev Med.* Dec 2007;33(6 Suppl):S349-356.
21. IOM, ed *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC2001.
22. Grimshaw J, McAuley LM, Bero LA, et al. Systematic reviews of the effectiveness of quality improvement strategies and programmes. *Qual Saf Health Care.* Aug 2003;12(4):298-303.
23. Shelley D, Cantrell J. The effect of linking community health centers to a state-level smoker's quitline on rates of cessation assistance. *BMC Health Serv Res.* 2010;10:25.
24. Bentz CJ, Bayley KB, Bonin KE, et al. Provider feedback to improve 5A's tobacco cessation in primary care: a cluster randomized clinical trial. *Nicotine Tob Res.* Mar 2007;9(3):341-349.

25. Wadland WC, Holtrop JS, Weismantel D, Pathak PK, Fadel H, Powell J. Practice-based referrals to a tobacco cessation quit line: assessing the impact of comparative feedback vs general reminders. *Ann Fam Med.* Mar-Apr 2007;5(2):135-142.
26. Petersen LA, Woodard LD, Urech T, Daw C, Sookanan S. Does pay-for-performance improve the quality of health care? *Ann Intern Med.* Aug 15 2006;145(4):265-272.
27. Sonnad SS. Organizational tactics for the successful assimilation of medical practice guidelines. *Health Care Manage Rev.* Summer 1998;23(3):30-37.
28. Ramseier CA, Warnakulasuriya S, Needleman IG, et al. Consensus Report: 2nd European Workshop on Tobacco Use Prevention and Cessation for Oral Health Professionals. *Int Dent J.* Feb 2010;60(1):3-6.
29. An LC, Bluhm JH, Foldes SS, et al. A randomized trial of a pay-for-performance program targeting clinician referral to a state tobacco quitline. *Arch Intern Med.* Oct 13 2008;168(18):1993-1999.
30. Coleman T. Do financial incentives for delivering health promotion counselling work? Analysis of smoking cessation activities stimulated by the quality and outcomes framework. *BMC Public Health.* 2010;10:167.
31. Roski J, Jeddeloh R, An L, et al. The impact of financial incentives and a patient registry on preventive care quality: increasing provider adherence to evidence-based smoking cessation practice guidelines. *Prev Med.* Mar 2003;36(3):291-299.
32. Davies P, Walker AE, Grimshaw JM. A systematic review of the use of theory in the design of guideline dissemination and implementation strategies and interpretation of the results of rigorous evaluations. *Implement Sci.* 2010;5:14.
33. Cantrell J, Shelley D. Implementing a fax referral program for quitline smoking cessation services in urban health centers: a qualitative study. *BMC Fam Pract.* 2009;10:81.
34. Shelley D. Implementing tobacco use treatment guidelines in dental clinics. *Journal of Dental Education.* accepted.
35. Shelley D, Anno J, Tseng TY, et al. Implementing tobacco use treatment guidelines in public health dental clinics in New York City. *Journal of Dental Education.* Apr 2011;75(4):527-533.
36. Shelley D, Jannat-Khah D, Wolff M. Tobacco-use treatment in dental practice: how Healthy People 2020 aligns federal policy with the evidence. *Journal of the American Dental Association.* Jun 2011;142(6):592-596.
37. Ajzen I. The theory of planned behavior. *Organizational Behavior and Human Decision Processes.* 1991;50(2):179-211.
38. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci.* 2009;4:50.
39. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: systematic review and recommendations. *Milbank Q.* 2004;82(4):581-629.
40. Solberg LI. Improving medical practice: a conceptual framework. *Ann Fam Med.* May-Jun 2007;5(3):251-256.
41. Ferlie EB, Shortell SM. Improving the quality of health care in the United Kingdom and the United States: a framework for change. *Milbank Q.* 2001;79(2):281-315.
42. Greenhalgh T, Wessely S. 'Health for me': a sociocultural analysis of healthism in the middle classes. *Br Med Bull.* 2004;69:197-213.
43. Simpson DD. A conceptual framework for transferring research to practice. *J Subst Abuse Treat.* Jun 2002;22(4):171-182.
44. Simpson DD. A conceptual framework for drug treatment process and outcomes. *J Subst Abuse Treat.* Sep 2004;27(2):99-121.
45. Simpson DD, Dansereau DF. Assessing organizational functioning as a step toward innovation. *Sci Pract Perspect.* Apr 2007;3(2):20-28.
46. Weiner BJ. A theory of organizational readiness for change. *Implement Sci.* 2009;4:67.
47. Bandura A, ed *Social foundations of thought and action: A social cognitive theory.*: Prentice-Hall, Englewood Cliffs, NJ; 1986.
48. Ajzen I. Perceived Behavioral Control, Self-Efficacy, Locus of Control, and the Theory of Planned Behavior1. *Journal of Applied Social Psychology.* 2002;32(4):665-683.

49. Manstead ASR, van der Pligt J. Should We Expect More From Expectancy-Value Models of Attitude and Behavior? *Journal of Applied Social Psychology.* 1998;28(15):1313-1316.

50. Godin G, Belanger-Gravel A, Eccles M, Grimshaw J. Healthcare professionals' intentions and behaviours: a systematic review of studies based on social cognitive theories. *Implement Sci.* 2008;3:36.

51. Grimshaw JM, Zwarenstein M, Tetroe JM, et al. Looking inside the black box: a theory-based process evaluation alongside a randomised controlled trial of printed educational materials (the Ontario printed educational message, OPEM) to improve referral and prescribing practices in primary care in Ontario, Canada. *Implement Sci.* 2007;2:38.

52. Walker AE, Grimshaw JM, Armstrong EM. Salient beliefs and intentions to prescribe antibiotics for patients with a sore throat. *Br J Health Psychol.* Nov 2001;6(Part 4):347-360.

53. Francis JJ, Eccles MP, Johnston M, et al. Explaining the effects of an intervention designed to promote evidence-based diabetes care: a theory-based process evaluation of a pragmatic cluster randomised controlled trial. *Implement Sci.* 2008;3:50.

54. ADA. 2008; http://www.ada.org/news/2110.aspx.

55. Havlicek D, Stafne E, Pronk NP. Tobacco cessation interventions in dental networks: a practice-based evaluation of the impact of education on provider knowledge, referrals, and pharmacotherapy use. *Prev Chronic Dis.* Jul 2006;3(3):A96.

56. Bellg AJ, Borrelli B, Resnick B, et al. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychol.* Sep 2004;23(5):443-451.

57. Kiefe CI, Allison JJ, Williams OD, Person SD, Weaver MT, Weissman NW. Improving quality improvement using achievable benchmarks for physician feedback: a randomized controlled trial. *JAMA.* Jun 13 2001;285(22):2871-2879.

58. Theobald M, Jaen CR. An update on tobacco cessation reimbursement. *Fam Pract Manag.* May 2006;13(5):75-76, 78.

59. NYSDOH. accessed 10-27-10; http://www.nyhealth.gov/health_care/medicaid/program/update/2008/2008-10.htm#med.

60. Solberg LI, Asche SE, Margolis KL, Whitebird RR. Measuring an organization's ability to manage change: the change process capability questionnaire and its use for improving depression care. *Am J Med Qual.* May-Jun 2008;23(3):193-200.

61. Conroy MB, Majchrzak NE, Silverman CB, et al. Measuring provider adherence to tobacco treatment guidelines: a comparison of electronic medical record review, patient survey, and provider survey. *Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco.* Apr 2005;7 Suppl 1:S35-43.

62. Stange KC, Zyzanski SJ, Smith TF, et al. How valid are medical records and patient questionnaires for physician profiling and health services research? A comparison with direct observation of patients visits. *Medical care.* Jun 1998;36(6):851-867.

63. Pbert L, Adams A, Quirk M, Hebert JR, Ockene JK, Luippold RS. The patient exit interview as an assessment of physician-delivered smoking intervention: a validation study. *Health Psychol.* Mar 1999;18(2):183-188.

64. Ritzwoller DP, Sukhanova A, Gaglio B, Glasgow RE. Costing behavioral interventions: a practical guide to enhance translation. *Ann Behav Med.* Apr 2009;37(2):218-227.

65. Park E, Eaton CA, Goldstein MG, et al. The development of a decisional balance measure of physician smoking cessation interventions. *Prev Med.* Oct 2001;33(4):261-267.

66. D'Aunno T. The role of organization and management in substance abuse treatment: Review and roadmap. *J Subst Abuse Treat.* Oct 2006;31(3):221-233.

67. Knudsen HK, Ducharme LJ, Roman PM. Early adoption of buprenorphine in substance abuse treatment centers: data from the private and public sectors. *J Subst Abuse Treat.* Jun 2006;30(4):363-373.

68. Knudsen HK, Roman PM, Oser CB. Facilitating Factors and Barriers to the Use of Medications in Publicly Funded Addiction Treatment Organizations. *J Addict Med.* Jun 2010;4(2):99-107.

69. Bride BE, Abraham AJ, Roman PM. Organizational factors associated with the use of contingency management in publicly funded substance abuse treatment centers. *Journal of Substance Abuse Treatment.*In Press, Corrected Proof.

70. Roman PM, Ducharme LJ, Knudsen HK. Patterns of organization and management in private and public substance abuse treatment programs. *J Subst Abuse Treat.* Oct 2006;31(3):235-243.
71. Johnson KM, Lando HA, Schmid LS, Solberg LI. The GAINS project: outcome of smoking cessation strategies in four urban Native American clinics. Giving American Indians No-smoking Strategies. *Addictive behaviors.* Mar-Apr 1997;22(2):207-218.
72. Laird NM, Ware JH. Random effects models for longitudinal data. *Biometrics.* 1982;38:963-974.
73. Pinheiro JC, Bates DM. *Mixed-effects models in S and S-PLUS*. New York: Springer-Verlag; 2004.
74. Zwarenstein M TS, Gagnier JJ, et al Improving the reporting of pragmatic trials. *BMJ.* 2008;337:a2390.
75. Fitzmaurice GM, Laird NM, Ware JH. *Applied longitudinal analysis*. Hoboken, NJ: John Wiley & Sons; 2004.
76. Braithwaite RS MS. Identifying favorable-value cardiovascular health services. *Am J Manag Care.* 2011;17(6):431-438.
77. DB. P, ed *2000.* 2nd edition ed. New York: Oxford; Meta-Analysis, Decision Analysis, and Cost-Effectiveness Analysis: Methods for Quantitative Synthesis in Medicine.
78. Weinstein MC TE, Sandberg EA, Neumann PJ, Evans JS, Kuntz KM, et al. . Modeling for health care and other policy decisions: uses, roles, and validity. *Value Health.* 2001;4(5):348-361.
79. PJ S, ed *Thematic text analysis: new agendas for analyzing text content*: Lawrence Erlbaum Associates; 1997.
80. J C, ed *Qualitative inquiry and research design: Choosing among five traditions*. Thousand Oaks, CA: Sage; 1998.
81. M MJ, ed *Designing funded qualitative research. Handbook of qualitative research* 2nd ed ed. Thousand Oaks, CA: Sage; 1994. (Eds.) INKDYSL, ed.
82. Pbert L, Adams A, Quirk M, Hebert JR, Ockene JK, Luippold RS. The patient exit interview as an assessment of physician-delivered smoking intervention: a validation study. *Health psychology : official journal of the Division of Health Psychology, American Psychological Association.* Mar 1999;18(2):183-188.
83. Thompson SG, Warn DE, Turner RM. Bayesian methods for analysis of binary outcome data in cluster randomized trials on the absolute risk scale. *Stat Med.* Feb 15 2004;23(3):389-410.
84. West M. Bayesian regression analysis in the "large p, small n" paradigm. *http://ftp.isds.duke.edu/WorkingPapers/0022.ps.* 2007.
85. Pbert L, Fletcher KE, Flint AJ, Young MH, Druker S, DiFranza J. Smoking prevention and cessation intervention delivery by pediatric providers, as assessed with patient exit interviews. *Pediatrics.* Sep 2006;118(3):e810-824.
86. Pbert L, Flint AJ, Fletcher KE, Young MH, Druker S, DiFranza JR. Effect of a pediatric practice-based smoking prevention and cessation intervention for adolescents: a randomized, controlled trial. *Pediatrics.* Apr 2008;121(4):e738-747.
87. Donner A, Klar N. Statistical considerations in the design and analysis of community intervention trials. *J Clin Epidemiol.* Apr 1996;49(4):435-439.
88. Horton NJ LS. Review of software to fit generalized estimating equation regression models. *American Statistician.* 1999;53:160-169.
89. CDC. Vital signs: Current cigarette smoking among adults aged >or=18 years --- United States, 2009. *MMWR Morb Mortal Wkly Rep.* Vol 59. 2010/09/11 ed2010:1135-1140.