

Title: Enhancing systems-level tobacco interventions in substance abuse treatment programs

Abstract

Substance abuse treatment program (SATP) patients are four times more likely to smoke than non-substance users, and also suffer high rates of tobacco-related disease and mortality. In 2008, regulations mandated smoke-free policies in all New York State SATPs, including a smoke-free environment, smoking cessation training for staff, and identification and treatment of all smokers. However, multiple national surveys continue to demonstrate low levels of tobacco cessation treatment in SATPs. Among the barriers to provision of cessation services in SATPs is limited staff capacity to address tobacco use. The proposed project will address this need by building capacity for multi-disciplinary tobacco cessation treatment at both provider and system levels in a large multi-site SATP serving approximately 4000 opioid dependent drug users.

The goals of the proposed project are to increase identification of tobacco use in SATP patients, to provide evidence-based smoking cessation treatment to all SATP patients who smoke, and to improve cessation rates among smokers with co-occurring substance use disorders. The project addresses both provider- and healthcare system-level approaches to tobacco use among smokers with comorbid substance abuse disorders. It achieves this by leveraging the infrastructure of the Einstein-Montefiore Division of Substance Abuse, which has a strong track record of delivering integrated primary medical care and substance abuse treatment to economically disadvantaged, racial/ethnic minority patients. In addition, the proposal focuses on a special population disproportionately burdened by smoking, goes beyond educating health professionals to address system change, and assesses not only smoking cessation treatment practices, but also smoking cessation outcomes.

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1. Overall Goals & Objectives

Goals

- To increase identification of tobacco use in substance abuse treatment program (SATP) patients.
- To provide evidence-based smoking cessation treatment to all SATP patients who smoke.
- To improve tobacco cessation rates among smokers with co-occurring substance use disorders.

The project aligns with the focus of the RFP by addressing both provider- and healthcare system-level approaches to tobacco use among smokers with comorbid substance abuse disorders, so that all smokers can be helped to quit. It achieves this by leveraging the infrastructure of the Einstein-Montefiore Division of Substance Abuse (DoSA), which has a strong track record of delivering integrated primary medical care and substance abuse treatment to economically disadvantaged, racial/ethnic minority group patients. In addition, our proposal focuses on a special population disproportionately burdened by smoking, goes beyond educating health professionals to address system change, and assesses not only smoking cessation treatment practices but also smoking cessation outcomes among SATP patients.

Objectives

(1) We will develop and deliver smoking cessation training to the following clinicians working within the Einstein-Montefiore Division of Substance Abuse (DoSA): eighteen clinical supervisors, 100 substance abuse counselors, and 22 medical providers (primary care physicians, physician assistants, and nurse practitioners). The Einstein-Montefiore DoSA system serves approximately 4000 opioid-dependent current and former drug users in the Bronx, New York, providing integrated medical care and substance abuse treatment in three separate sites.

(2) To aid DoSA clinicians in identifying smokers and providing smoking cessation treatment, we will develop, implement, and evaluate three electronic health record (EHR) field prompts. These prompts will remind all DoSA clinicians to: (i) assess tobacco use and gauge interest in quitting; (ii) refer interested smokers to the New York State Smokers' Quitline; and (iii) prescribe smoking cessation pharmacotherapy to all interested smokers. These prompts will be adapted for the substance abuse treatment setting from an existing EHR algorithm that is currently in use in Montefiore's large ambulatory care network.

The combination of smoking cessation training and specific, automated EHR prompts will increase identification of smokers and provision of evidence-based cessation treatment, which will in turn increase tobacco cessation rates among SATP patients who smoke.

2. Technical Approach

2.a. Current assessment of need

How will this project meet the goal of the specific area of interest for the RFP?

Substance abuse treatment program (SATP) patients are four times more likely to smoke than non-substance users, and also suffer high rates of tobacco-related disease and mortality.¹⁻³ In 2008, regulations mandated smoke-free policies in all New York State SATPs, including a smoke-free environment, smoking cessation training for staff, and identification and treatment of all smokers. Though studies have shown that SATP clinicians increased their provision of tobacco-related advice, treatment, or referral in the year following implementation of the New York State policy, only a minority of SATP staff attended on-line or in-person training, and tobacco cessation rates in outpatient SATPs have not significantly changed in recent years.^{4,5} Multiple national surveys continue to demonstrate low levels of tobacco cessation treatment in SATPs.^{6,7} Among the barriers to provision of smoking cessation services in SATPs is limited staff capacity to address tobacco use. The proposed project will address this need by building capacity for multi-disciplinary tobacco cessation treatment at both provider and system levels in a large multi-site SATP serving approximately 4000 opioid dependent current and former drug users.

2.a.i. Baseline data

We have conducted a series of studies demonstrating *high prevalence of smoking, incomplete documentation of smoking status, and low rates of smoking cessation pharmacotherapy prescription* in the Einstein-Montefiore substance abuse treatment system. In a 2006 cross sectional survey of a convenience sample of 389 DoSA methadone patients, 83% were smokers, and 70% of smokers reported interest in quitting.⁸ In 2013 we updated these data, performing a comprehensive chart review to identify smoking prevalence among *all* patients at two of the three DoSA sites. We found that the proportion of DoSA patients who smoke had remained exactly 83%, and that only 28% had been prescribed any smoking cessation pharmacotherapy over a four year period.¹⁰ In another survey/chart review study at a closely affiliated Montefiore center with a large primary care-based buprenorphine treatment program for opioid-dependent persons, we found that 67% of buprenorphine treatment patients were smokers, but many (22%) did not have smoking status documented in their medical records and only 17% had been prescribed smoking cessation medication.⁹ These data demonstrate not only extraordinarily high prevalence of smoking among opioid-dependent substance abuse treatment patients in the Bronx, but also incomplete documentation of smoking status and relatively low rates of pharmacotherapy prescription.

Telephone Quitlines are a free service with wide potential reach, and generally offer telephone counseling, educational materials, and nicotine replacement therapy. Regarding the New York State Quitline, we assessed its use among methadone-maintained smokers enrolled in a randomized controlled varenicline trial who were offered facilitated NYS Quitline referral as

part of smoking cessation counseling. We found that, despite challenges with consistent telephone service, a sizeable minority (22%) of smokers used the NYS Quitline.¹¹ *To aid cessation success, however, the number of active Quitline users needs to be higher.* Though studies have shown that facilitated referral to Quitlines by medical providers increases quitline utilization over self-referral, smokers in substance abuse treatment may need additional support to obtain the full benefit of Quitline services. Quitline-based counseling has been shown to be efficacious among racial and ethnic minority smokers, and should be an integral part of a comprehensive smoking cessation program in an SATP.^{12,13}

2.a.ii. Primary audience targeted for this project: who will directly benefit?

By targeting the staff of the Einstein-Montefiore Division of Substance Abuse for enhanced training and electronic decision-making support to offer smoking cessation counseling to all patients, this project will directly benefit smokers in substance abuse treatment in the Bronx. The Bronx is one of the nation's poorest, and most racially and ethnically diverse, counties. One-third of the Bronx population lives below the poverty line, and the burden of tobacco-related illnesses, including cardiovascular disease and asthma, greatly exceeds national norms. The sociodemographic characteristics of the Bronx are reflected in DoSA's patient population, which is 24% African American, 59% Hispanic, and 17% Caucasian. Approximately 38% are female. Most DoSA patients (45%) are over 50 years old; only 17% are 18-39 years old and 38% are 40-49 years old. Eighty-one percent of DoSA patients have incomes \leq 100% of the federal poverty limit. DoSA's mission is to provide pharmacotherapy, counseling and related services, and primary medical care to approximately 4000 adults (18 years or older) with addiction to opioids. Treatment generally includes methadone maintenance, as well as buprenorphine maintenance and long-term detoxification. We have found, on repeated assessments, that smoking prevalence among DoSA patients is over 80%, far exceeding national, state, city, or borough-wide estimates of the rate of smoking among adults.

Our proposed training will target DoSA clinical providers (counseling supervisors, counselors and medical providers), with approximately two-thirds (100/140) of the targeted providers being substance abuse counselors. Their mean age is 41 years; 71% are women; 40% are African American, 38% are Hispanic, 18% are Caucasian, and 4% are Asian. Thirty-one per cent are certified as Credentialed Alcoholism and Substance Abuse Counselors (CASAC), and 41% are in recovery from substance use. All three DoSA sites have a unified Executive Director (Dr. Church, see Letter of Support), and Research Director (Dr. Arnsten). Each has an on-site administrator with local authority over policies and procedures. There is a monthly meeting of administrators and counseling supervisors from all sites, and weekly meetings of substance abuse counselors and medical providers at each site. Project staff will attend all regular DoSA clinician meetings during the year-long project. All project activities will be targeted to DoSA clinical and medical staff, and outcomes will be assessed among both DoSA staff and DoSA patients, using administrative and chart review data to assess provider-, system- and patient-level outcomes.

2.b. Project Design and Methods

Enhanced smoking cessation training

To achieve our first objective, a physician with clinical and research expertise in addiction medicine and tobacco control (Dr. Nahvi) will develop separate smoking cessation trainings for (1) counselors and clinical supervisors, and (2) medical providers. Trainings will be provided at each DoSA site and will accommodate staff schedules to ensure broad reach. Topics will include: the burden of tobacco use among individuals with substance use disorders, stages of behavioral change, evidence-based smoking cessation treatments, including Quitlines and pharmacotherapy, and misperceptions about the potential adverse impact of addressing tobacco use in substance abuse treatment. Trainings will also provide an experiential component, with feedback on cessation counseling skills.

In addition to group and individual training, written materials will be disseminated to all DoSA clinical providers. These will include patient education brochures, a guide to the New York State Smokers' Quitline web-based referral system, and a pharmacotherapy guide describing cessation medication dosing, duration, precautions, and side effects. All materials will be available in English and Spanish. Finally, public service announcements, suitable for mounting in waiting and treatment areas, will be made available to all DoSA sites.

Electronic decision support

To achieve our second objective, we will develop DoSA-specific electronic health record (EHR) prompts to enable efficient, widespread implementation of tobacco screening and treatment interventions. Screening and decision support algorithms will be programmed into DoSA's EHR and will be available to all DoSA providers. A similar algorithm has been developed and is in use in Montefiore's ambulatory care network (see screen shot below); this algorithm, which will be adapted for use in DoSA, provides guidance in the form of short scripts and other prompts to assist clinicians to: (a) ask about smoking and other tobacco use; (2) assess motivation to quit smoking; (3) offer quitting advice appropriate to the patient's stage of readiness to quit, including advice to use the New York State Quitline; and (4) offer pharmacotherapy and/or additional resources, if warranted.

DoSA patients currently complete treatment plans with substance abuse counselors every six months. The treatment plan form in the EHR will include a prompt for counselors to assess tobacco use and interest in quitting, and this prompt will lead to an algorithm (as described above). For patients who report interest in quitting (i.e., contemplation or preparation stage of change), an order field will pop up, prompting counselors to complete a web-based referral to the NYS Quitline. Our prior data demonstrate that the NYS Quitline, despite being a free, proactive service in which smokers are contacted by Quitline staff, is underutilized by substance abuse treatment patients who are actively trying to quit smoking. By automating the referral process and educating counselors and their supervisors about the Quitline, we anticipate that

Quitline usage will rise and more smokers will be successful in their quit attempts. To assess Quitline usage, the New York State Quitline will provide patient-level follow-up reports, with aggregate data on center referrals.

All three DoSA sites offer integrated primary medical care and substance abuse treatment. Medical providers see patients at least annually, with more frequent visits as needed. After implementation of the new EHR algorithm, the annual physical exam and medical visit forms will include a prompt for medical providers to assess tobacco use and interest in quitting. As above, for patients who report interest in quitting and willingness to use pharmacotherapy, electronic order sets will pop up, allowing medical providers to prescribe any of the FDA-approved smoking cessation medications. Currently, most DoSA patients (>80%) are insured by Medicaid, which in NY State provides for up to 180 days of smoking cessation yearly. For the minority (<20%) of DoSA patients who are uninsured or have inactive Medicaid, we will stock nicotine patches, gum, and varenicline at the DoSA central pharmacy.

Summary | **Pharmacotherapy**

Bronx Breathes Adult Tobacco Cessation Form V 1.5

ASK

Tobacco Use: **Quit Plan:**
Reasons to Quit:
Fax to Quit Form:

cigarettes
 little cigars/cigarillos
 hookah/water pipe
 cigars

This should be done in a clear, strong and personalized manner – urge every smoker to quit:

- Personalized: - Help patient to identify a strong motivating factor (conviction)
- Tie tobacco use to current health concerns/illness/medications and the impact tobacco use has on children and others in household (e.g., "Continuing to smoke makes your asthma worse, and quitting may dramatically improve your health.") Or "Quitting smoking may reduce the number of ear infections your child has."

ASSESS

Is the patient ready to quit? yes no

ASSIST

Help patient with a quit plan:

Practice problem-solving methods Reviewed strategies that helped during previous quit attempts.
 Provide support through the office as part of the treatment. Help identify someone to support his/her decision at home and at work.
 Will document the extent of intervention on the patient's chart for assessment of quit attempt at the next visit.
 * Length of counselling: (mins)
 Recommend use of approved medication – OTC (NRT), Rx (referral to MD)
 Referred to a smoking cessation program.

ARRANGE

Assess smoking status at every visit. Reinforce steps patient is taking to quit. **Quit Plan:**
 Ask patient about the quitting process. Provide encouragement. **Fax to Quit Form:**

Comment:

2.c. Evaluation Design

2.c.i. Determining whether practice gap was addressed

Data sources

All outcomes will be derived from DoSA administrative data, which includes EHR data and billing data. Administrative data offers an efficient means to gather data while addressing research questions of relevance to both medical leaders and policy makers. In the Einstein-Montefiore DoSA system, both billing and quality control are managed through the electronic information system; consequently, there are high system incentives as well as checks to ensure that data accurately reflect what happens during clinical encounters.

Evaluation model

The RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) evaluation model (see below) will be used to assess the effectiveness of smoking cessation training and EHR prompts 6 and 12 months after implementation. We will assess effectiveness by measuring treatment practices (provision of Quitline referral and/or pharmacotherapy) by DoSA counselors and medical providers, and by assessing smoking status and quit attempts in a random sample of 100 DoSA patients during each month of the year-long project.

The RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) evaluation model (Table) is commonly used to assess the public health impact of an intervention.^{16,17} It facilitates a rigorous and comprehensive evaluation of interventions delivered in “real-world” settings, and is well-suited to evaluation of health services programs that affect systems and processes of care. RE-AIM has been used to assess the effectiveness of a variety of interventions, including smoking cessation.^{18,19}

RE-AIM evaluation model		
<i>Dimension</i>	<i>Definition</i>	<i>Level</i>
Reach	Proportion of the target population that participates in the intervention	Individual (clinical provider)
Effectiveness	Success rate, defined as positive outcomes minus negative outcomes	Individual clinical provider <i>and</i> patient
Adoption	Proportion of setting that adopt the intervention	System (DoSA)
Implementation	Extent to which the intervention is implemented as intended	System (DoSA)
Maintenance	Extent to which the program is sustained over time	Individual (provider) and system (DoSA)

Patient-level outcomes

In addition to assessing treatment practices by DoSA clinicians before and after implementation of the intervention, we will also assess smoking behavior by individual DoSA patients. Every month the Project Director will review 100 charts chosen at random from each site (total of 300 charts), and will note whether the patient's smoking status was documented, whether the patient smokes, whether an intervention was given (either a referral to the Quitline or other local program, a prescription for pharmacotherapy, or in-person tobacco counseling), and whether a quit attempt was made. No protected health information will be recorded.

Data Collection and Analysis

To assess the impact of the proposed intervention on tobacco treatment practices (provision of counseling, Quitline referral, or pharmacotherapy) by substance use treatment center staff (medical providers and substance abuse counselors), we will perform chart audits monthly during the year-long project. In addition, each month the Project Director will review 100 charts chosen at random from each site (total of 300 charts), noting whether the patient's smoking status was documented, whether the patient smokes, whether a documented intervention was given (either a referral to the Quitline or other local program, a prescription for pharmacotherapy, or in-person tobacco counseling), and whether a quit attempt was made. In addition, we will quantify the number of referrals to the New York State Smoker's Quitline made by each site.

The primary outcome will be documentation (yes/no) of a tobacco treatment intervention (i.e. any of the following: referral to New York State Smoker's Quitline; prescription of tobacco dependence pharmacotherapy; referral to a local tobacco group program; delivery of individual counseling by a provider or counselor) which will be assessed by audits of charts from each site. We will estimate and compare the proportion of patients that have documented tobacco treatment intervention before and after intervention implementation. Logistic regression using Generalized Estimating Equations (GEE) will be employed to estimate the magnitude of pre- and post-intervention differences in the proportion of charts with documented tobacco treatment. GEE will permit the estimation of appropriate standard errors given correlated responses arising from repeated measures. Site-specific estimates of pre- and post-intervention differences will also be evaluated.

Use of control group

We will employ a pre-post intervention design to analyze intervention effect, allowing each site to serve as its own control.

2.c.ii. Quantification of anticipated change

We anticipate the following outcomes after implementation of the proposed intervention:

Measure (population)	Rate before intervention	Rate after intervention
Quitline referral (among all smokers interested in quitting)*	5%	35%
Pharmacotherapy prescription (among all smokers interested in quitting)	25%	50%
Successful smoking cessation (among all smokers)	5%	15%

*estimating 70% interested in quitting, of whom 50% will initially accept referral

2.c.iii. Was the target audience fully engaged in the project?

To assess reach and adoption, we will determine the proportion of counselors and medical providers who: (1) attend smoking cessation trainings and participate in experiential learning exercises, (2) utilize written materials provided at the trainings, (3) respond to EHR prompts during clinical encounters. These feasibility and process measures will be assessed in addition to our outcome measures.

2.c.iv. Dissemination

We will disseminate trainings modules with the Smoking Cessation Leadership Committee Tobacco Free for Recovery Network, the Providers' Clinical Support System for Medication Assisted Treatment, and the New York State Office of Alcoholism and Substance Abuse Services provider training website. We will publish findings of our evaluations in peer-reviewed tobacco control and substance abuse journals.

3. Detailed Workplan and Deliverables - Narrative

The proposed project builds on the close clinical and research collaboration between the investigators (Drs. Nahvi, Arnsten, and Ning) and the Einstein-Montefiore Division of Substance Abuse. Our group has previously described the markedly high prevalence of tobacco use among substance abuse treatment patients, the low rate of screening for tobacco use among buprenorphine treatment patients, the limited provision of smoking cessation pharmacotherapy to DoSA patients who smoke, and the feasibility of routine, facilitated telephone quitline referral among methadone maintained smokers. From 2008-2014, the Dr. Nahvi was also Co-Investigator of Bronx BREATHEs, a New York State Department of Health-funded tobacco control program that provided training and technical assistance to enhance identification and treatment of tobacco use. The proposed project will leverage the Bronx BREATHEs team's experience developing educational presentations and EHR tobacco screening and decision support algorithms. Prior work by Bronx BREATHEs investigators demonstrated a

marked increase in telephone quitline referral among Bronx healthcare providers with a program of provider training and technical support.¹⁵

Dr. Nahvi is a new investigator in smoking cessation research who is quickly developing a significant reputation for her expertise in treating tobacco dependence among persons with co-occurring substance abuse disorders. With KL2 funding from the Einstein-Montefiore NIH-funded Institute for Clinical and Translational Research (ICTR), Dr. Nahvi conducted a pilot randomized, double-blind, placebo-controlled trial of varenicline for smoking cessation among methadone maintenance patients. She is now Principal Investigator of a NIDA-funded K23 award to determine whether methadone clinic-based directly observed varenicline therapy is associated with increased varenicline adherence and improved tobacco abstinence; a manuscript describing the rationale and design of this trial was recently published. For this project, Dr. Nahvi will oversee development and implementation of the smoking cessation training and the electronic health record (EHR) prompts, as well as data management/analysis and dissemination of research findings. She is extremely well-suited to this role, as she was the lead educator for our Bronx BREATHE program. She will also directly supervise the Project Manager, and will work closely with Co-Investigators Drs. Arnsten and Ning and with DoSA staff. As a part-time medical provider in DoSA, Dr. Nahvi is already integrated into the DoSA system.

In the table below, each element of the proposed workplan is listed, along with a projected timeline and the individual who will be responsible.

4. Detailed Workplan and Deliverables - Table

Month	Activity
1	Hire Project Director (Nahvi)
1	Schedule regular investigator meetings (Nahvi, Arnsten, Ning)
1	Obtain expedited IRB approval (Nahvi)
1	Develop trainings for counselors and medical providers (Nahvi, Arnsten)
1	Begin to adapt Montefiore EHR algorithm for use in DoSA (Nahvi, Arnsten)
1	Begin work with Research Informatics Core (RIC) to develop database, select data elements, develop/implement data synthesis process (Nahvi, Ning, RIC)
2	Regular investigator meetings (Nahvi, Arnsten, Ning)
2	Revise EHR algorithm(Nahvi, Arnsten, RIC)
2	Begin chart audits to asses tobacco prevalence and cessation treatment (Ning, RIC)
2	Begin manual chart reviews (100 charts per site) to assess patient-level outcomes (Project Director)
3	Continue investigator meetings (Nahvi, Arnsten, Ning, PD)
3	Finalize training modules (Nahvi)
3	Finalize EHR algorithm(Nahvi, Arnsten, RIC)
3	Continue chart audits (Ning, RIC)
3	Continue manual chart reviews (PD)
4-7	Continue investigator meetings (Nahvi, Arnsten, Ning, PD)
4-7	Deliver smoking cessation trainings at all three sites (Nahvi)
4-7	Implement EHR algorithm in DoSA (Nahvi, Arnsten, RIC)
4-7	Continue chart audits (Ning, RIC)
4-7	Continue manual chart reviews (PD)
8	Begin post-intervention data collection (PD, RIC)
8-10	Continue investigator meetings (Nahvi, Arnsten, Ning, PD)
8-10	Continue chart audits (Ning, RIC)
8-10	Continue manual chart reviews (PD)
8-10	Continue investigator meetings (Nahvi, Arnsten, Ning, PD)
11-12	Disseminate findings

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