

## A. Cover Page

Project Title: Linking low SES and racial/ethnic minority populations to evidence-based cessation treatment through health system changes

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Main collaborators: New York University School of Medicine, Roswell Park Cancer Institute- New York State Smokers' Quitline, New York City Department of Health and Mental Hygiene- Primary Care Information Project, Betances Community Health Center, Upper Room AIDS Ministry

### **Abstract**

With the adoption of electronic health records, the New York State Smokers' Quitline (NYSSQL) paper-based fax referral system is becoming obsolete. In response to this practice transformation the NYSSQL launched Opt-to-Quit (OTQ). OTQ is a policy-driven, system-wide solution for facilitating smoker referrals through a streamlined electronic data exchange between the NYSSQL and the healthcare organization. Due to barriers in implementation few healthcare organizations have adopted the OTQ referral model; specifically none in New York City (NYC). The goal of the proposed project is to implement OTQ in two Federally Qualified Health Centers (FQHCs) that serve low socioeconomic status (SES) and racial/ethnic minority populations in NYC to ensure disparate populations are receiving evidence-based smoking cessation treatment. A multi-level evaluation, using RE-AIM (reach, effectiveness, adoption, implementation and maintenance) as a framework, will be conducted to determine the extent to which the proposed project addresses the broad gap that exist between the number of low SES and racial/ethnic minorities served by FQHCs and the rate of smokers connected to NYSSQL. The evaluation emphasizes both process and outcome measures to ensure that we are able to assess both if the intervention worked and why it worked (i.e. What were the processes needed to implement OTQ). The primary goal of this proposal is to develop a highly replicable step-by-step protocol for implementing OTQ that addresses current barriers to adoption and results in higher rates of quitline referrals, increased engagement in treatment and improved cessation rates among low SES and racial/ethnic minority smokers.

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## C. Main Section

**3. Overall Goal & Objectives:** Our **primary goal** is to create a highly replicable and sustainable model for ensuring that Federally Qualified Health Centers (FQHCs) and other safety net systems that serve low socioeconomic status (SES) and racial/ethnic minority patient populations screen all patients for tobacco use, and offer all smokers opportunities to receive evidence-based treatment. The model leverages full adoption of electronic health records (EHRs) in two FQHCs, Upper Room Aids Ministry (URAM) and Betances Community Health Center (BCHC), and a robust evidence-based state Quitline to develop best practices for implementing Opt-to-Quit (OTQ). OTQ is a policy-driven and system wide solution for facilitating smoker referrals through streamlined data exchange between the New York State Smokers' Quitline (NYSSQL) and healthcare organizations (HCOs). Our proposed approach addresses the three key priorities specified in the RFP: 1) it goes beyond educating health professionals to address the system changes needed to create a population-based approach, therefore increasing the reach of evidence-based treatment to all smokers in two FQHCs, 2) measures organizational (quitline referrals), provider (tobacco screening and cessation assistance) and patient level outcomes (quit attempts and cessation), and 3) targets health care systems that serve populations disproportionately burdened by smoking. The primary goal aligns with the existing mission of the applicant organization which works to improve rates of tobacco screening and treatment in healthcare settings serving disparate populations across New York City (NYC). **Objectives:** By the end of year two, we will have: conducted a process evaluation to inform the development of a step by step protocol for implementing the OTQ program, including defining the resources needed (e.g. information technology (IT), staff); successfully implemented OTQ in two FQHCs in NYC; and conducted an outcome evaluation of OTQ on organizational, provider and patient level outcomes.

**4. Technical approach:** One of the most significant advances in tobacco control over the last decade has been the creation of statewide tobacco cessation quitlines. The Public Health Service (PHS) Guideline on Treating Tobacco Use and Dependence has documented the efficacy of quitlines. Yet, quitlines are grossly underutilized reaching only about 1-2% smokers annually.<sup>i</sup> One strategy for increasing the reach of quitlines is creating a referral system that links health care practices to the quitline via a fax, or more recently, electronic referral mechanism.<sup>ii</sup> Although the referral system offers providers the option to “delegate” counseling and treatment, barriers to implementing these systems (e.g. need for changes in workflow, and additional system changes) have resulted in poor rates of adoption. Studies have shown that even modest increases in the reach of quitlines could increase the impact on population level smoking prevalence.<sup>v</sup> Therefore it is critically important to develop methods for overcoming barriers to implementing quitline referral systems that are easy to use and optimize referral rates.

Currently, In New York State (NYS) referrals to the NYSSQL can be completed through a variety of different methods. Firstly, a healthcare provider can hand a patient an educational material with the NYSSQL's telephone number and website and encourage them to call/go online for assistance. The success of this methodology is solely dependent on the patient's initiative and motivation to pick up the phone, or go online to enroll in the NYSSQL services. The second and more effective method for referring patients is the fax-based program, known as Refer-to-Quit (RTQ) in NYS. RTQ requires the patient to provide their clinician their basic

contact information and sign a paper form that is then faxed to the NYSSQL. The NYSSQL then proactively calls the patient. Over the years NYUSOM has been successful in increasing rates of fax referrals to the NYSSQL despite encountering barriers including but not limited to: HCOs access to a fax machine; staff effort needed to fax the form; errors in the faxing process resulting in failed transmissions; paper forms getting misplaced at the HCO and NYSSQL; and NYSSQL manual data entry errors.

With EHR adoption, the RTQ program via fax is becoming obsolete, as HCOs have expressed that they no longer want to use paper-based systems. In response to this practice transformation, in 2012 the NYSSQL launched the OTQ program to facilitate more efficient referrals from health care systems to the quitline. OTQ is a policy-driven, PHS Guideline-aligned<sup>vi</sup> system-wide model that identifies all tobacco-using patients, and electronically refers each to the NYSSQL to engage in the quit process and offer additional quitline services, unless he or she opts out. One of the key innovations of OTQ is that it aims to increase patient engagement in evidence-based TDT by changing the NYSSQL referral program to a patient “opt-out,” whereby all identified smokers are systematically referred through the EHR, as opposed to an “opt-in” approach where only smokers who express interest in quitting are referred to NYSSQL. The “opt-out,” approach works as follows: Clinicians simply state to patients that as per the FQHCs organizational policy they will be connecting all patients to the NYSSQL, so long as the patient verbally consents. The EHR will be updated to contain a customized chart field to document and submit patient referrals. With the click of a button the EHR then automatically transmits the patient’s basic contact information (OTQ adheres to all Health Insurance Portability and Accountability Act (HIPAA) compliance requirements) to the NYSSQL; creating a registry of smokers. The NYSSQL will then call the patient within 72 hours, and connect them to evidence-based services.

Following the OTQ intervention, the NYSSQL then transfers secure, patient-level information back to the referral source including services provided (i.e.: has the patient chosen a quit date, were they mailed nicotine replacement therapy (NRT) etc.), creating a bi-directional data exchange system. Aggregate organizational-level data of all patients referred to the NYSSQL via OTQ can also be provided. With these reports FQHCs can track referral practices at the provider and organizational level. Additionally, they can also receive reports containing updated information regarding their patient’s quit attempts and smoking status.

Integrating an electronic referral program into the EHR has become increasingly more relevant as FQHC key decision-makers are required to systematically record rates of tobacco use assessment and treatment to meet regulatory standards and policy initiatives,<sup>i vii</sup> such as but not limited to: Meaningful Use, Patient-Centered Medical Home, and Health Resources and Services Administration Uniform Data System (HRSA UDS). Although OTQ provides an opportunity to increase the reach of quitline services, adoption and implementation have been slow. We propose to leverage the applicant’s combined expertise in tobacco control and implementation science to develop a model for integrating OTQ in two safety net health care systems.

#### **a. Current Assessment of Need in the target area**

**i. Baseline data:** The proposed project aims to address well-documented gaps in the delivery of evidence based TDT. Disparities in tobacco use and related illnesses also emphasize the need to

focus on health care settings serving vulnerable populations. According to the most recent data from the NYC Department of Health and Mental Hygiene (NYCDOHMH), smoking-related illnesses remain the leading cause of preventable death in NYC.<sup>viii</sup> The most recent 2014 data demonstrates that the adult smoking rate in NYC is currently 16.1% (over one million smokers), the highest it has been since 2007.<sup>ix</sup> While NYC smoking rates overall have declined over the past decade (21.5% in 2002 vs. 16.1% in 2014) significant tobacco use disparities exist.<sup>x</sup> According to the 2013 NYCDOHMH Community Health Survey (CHS), poverty is associated with higher rates of smoking (17.6% for those living below the federal poverty level vs 10.3% for those living above poverty level). Additionally, smokers were more likely to have a high school (18.7%) or less than high school (19.9%) education, as compared to a college education (11.4%).<sup>xi</sup> Data from the New York State Tobacco Control Program (NYSTCP) evaluation shows similar disparities by income and education. Disparities in smoking rates are driving health outcome inequalities for some of the most underserved people in NYC. Additional gaps that this proposal and future scale up of the proposed intervention will address are (1) persistent low rates of provider screening and cessation assistance, and (2) low rates of referrals from FQHCs to the NYSSQL.

*1. Low rates of screening and cessation assistance:* According to the 2012 Independent Evaluation Report of the NYSTCP, 76.6% of NYS smokers indicate that their health care provider advised them to quit and 50% of smokers in NYS report receiving cessation assistance. In addition, the 2012 Report showed that between 2007 and 2011, there were no statistically significant changes in the percentage of adult smokers who were advised to quit in the past 12 months when they visited a health care provider (76.6% in 2011 vs. 79.7% in 2007).<sup>xii</sup> This lack of recent improvement was also true for the percentage of smokers who reported that their health care provider assisted them with smoking cessation. The rate of cessation assistance was 49.9% in 2007 and 46.4% in 2011. The gap of provider screening and cessation intervention is further demonstrated through data from the NYCDOH’s Primary Care Information Project (PCIP) (Table 1). PCIP has created a data warehouse that is linked to the EHRs of over 600 primary care practices serving disparate populations. This link allows PCIP to query these practices and receive aggregated quality of care data on a daily basis. This data source also enables PCIP to conduct ongoing surveillance of adherence to tobacco use treatment guidelines. The data shows that the average rates of screening for tobacco use were 78.6% and the average rate of cessation interventions was 31.7%. *Although average rates of compliance with recommendations for screening tobacco users are high, compliance varies widely across the region, and compliance with recommendations for intervention remain poor.* HCOs face many common barriers in regards to adopting, integrating, and delivering the U.S. Preventive Services Task Force’s (USPSTF) TDT recommendations including time constraints and conflicting health priorities. Due to these barriers, US health professionals have reported they do not fully perform the recommended procedure of “Ask, Advise, Assess, Assist, Arrange” (5A’s). While many providers state they ask and advise about smoking, they report much less assessing, assisting and especially arranging follow-up<sup>xiii</sup>. The PHS Guidelines suggest that the 5A’s responsibilities can be shared between various health professionals.<sup>vi</sup> Telephone quitlines’ in

Table 1. PCIP data by County	Screening	Cessation intervention
Manhattan (New York)	75.7%	29.6%
Bronx	81%	33%
Queens	81.5%	28.9%
Brooklyn	77.9%	30.8%
Staten Island	77%	36.6%

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particular may play a key role in increasing all health professionals' involvement in providing TDT.<sup>v</sup> To mitigate the barriers outlined, OTQ will streamline the referral "assistance," easing the providers' burden.

**2. Low rates of referrals from HCOs to the NYSSQL:** A key health systems change strategy is to develop a well-defined referral mechanism from the HCO to the quitline. According to the 2013 CHS, among NYC adults who self-identified as current smokers 74.8% reported having a doctor or health care provider, indicating that HCOs are in a strategic position for referring smokers to the NYSSQL.<sup>xi</sup> This is consistent with data that demonstrates 70%-80% of smokers will see a provider each year.<sup>vi</sup>

Despite the large number of smokers that see a provider and the potential for patients to be connected to evidence-based TDT via the NYSSQL, this service is underutilized. According to NYSSQL data from 1/1/12-12/31/13, a total of 5878 referrals were received by NYC health care providers.<sup>xiv</sup> Given that an estimated 752,000 smokers in NYC report having one person or more than one person they think of as their personal doctor or health care provider, this indicates that less than one percent (0.8%) of smokers who report having a health care provider were referred to the NYSSQL via RTQ in 2013.<sup>xi</sup>

**ii. Primary Audience:** We propose to target two FQHCs that serve low SES, and racial/ethnic minorities: Upper Room Aids Ministry (URAM) and Betances Community Health Center (BCHC).

FQHCs are safety net providers, offering comprehensive care to underserved populations. *Table 2* shows 2013 data from HRSA's UDS comparing both FQHCs that will be implementing OTQ. Over 50% of URAM and BCHC patients receive Medicaid, and almost 90% of URAM and 76% of BCHC patients are earning at or below 100% of the poverty level. The high smoking rate at URAM (>70%) reflects the large number of patients with comorbid conditions (mental illness and substance use) who are also those at highest risk of tobacco use (*Table 3*). BCHC also has a smoking prevalence significantly higher than the general NYC populations (23% vs 16%). Developing a model for implementing OTQ in these sites, that can be disseminated to other FQHCs and safety net systems, will increase access to evidence based treatments among populations with the highest risk for tobacco-related morbidity and mortality.

*Table 3* shows data from January 1, 2012 to December 31, 2013. The results demonstrate the opportunity for improving guideline adherence at FQHCs. Only about 60% of patients at both sites are screened for tobacco use, a rate that should be closer to

	URAM	BCHC
Total patients served	3184	5044
% Racial and/or ethnic minority	92.4%	96.1%
% Black/African American	77.6%	12.3%
% Hispanic/ Latino ethnicity	31.6%	58.2%
% Patients at or below 100% of the poverty level	89.9%	76.5%
% Medicaid/CHIP	55.3%	52.4%
% Uninsured	28.2%	10%
% Patients with Hypertension	15.1%	25.2%
% Patients with Diabetes	9.6%	16.8%
% Patients with Asthma	15.5%	14.3%
% Patients with HIV	30.3%	5.4%

	HU/URAM		BCHC	
% of patients screened for tobacco use	1385 2190	<b>63%</b>	2622 4093	<b>64%</b>
% of patients identified as smokers (have smoked in the past 30 days)	998 1385	<b>72%</b>	595 2622	<b>23%</b>
% of Smokers offered assistance	438 998	<b>45%</b>	198 595	<b>33%</b>
# of NYSSQL faxed referrals between 2009-2014	<b>1</b>		<b>66</b>	
# of NYSSQL faxed referrals between 1/1/12-12/13/12	<b>0</b>		<b>31</b>	
# of NYSSQL faxed referrals between 2013-2014	<b>5</b>		<b>51</b>	

100%. A significant gap exists at both FQHCs between those being identified as smokers and the number being offered cessation assistance.

Furthermore, NYSSQL data demonstrates that only a small portion of smokers are referred to the NYSSQL via the traditional RTQ process.<sup>xiv</sup> Results from over the last five years (2009-2013) from the NYSSQL<sup>xiv</sup> demonstrated that the NYSSQL received only one fax referral from URAM, and over the past year (2013-2014) a total of five fax referrals were received. Over the last five years (2009-2013) only 66 referrals were sent to the NYSSQL from BCHC.

**b. Project Design and Methods:** The aim of this project is to develop a model for implementing OTQ in FQHCs to increase the referrals to the NYSSQL and reduce smoking prevalence among high risk populations. The project will address OTQ implementation barriers noted by the NYSSQL. These include a need to: obtain buy-in from leadership, clear definitions of staff and resource needs to implement OTQ including estimated budget impact, templates for adaptations required in the EHR and other data systems to facilitate data exchange between the FQHC and the NYSSQL, and a clear clinical pathway that defines roles and responsibilities related to the new system. In year one, we will: (1) conduct a baseline assessment of both FQHCs' including staffing, workflow, IT expertise, current systems for screening and documenting TDT, current systems for referring patients to the NYSSQL and updated TDT quality measures obtained from the EHR. We will also conduct a theory driven survey of each FQHC Medical Director to assess factors that may influence adoption and implementation of TDT guidelines (implementation climate, organizational readiness, and outcome expectancies), (2) form a quality improvement (QI) team and collaborative learning group that will include at least one champion from each site, (3) redesign workflow to integrate OTQ (4) update the EHR to enable providers to use OTQ system (5) update both FQHCs TDT policies and procedures (6) provide additional technical assistance (TA) in the form of trainings, (7) fully integrate OTQ in two FQHCs (8) maintain a tracking system to collect process measures used to analyze the early development and procedures involved in implementing OTQ. In Year two an (9) evaluation will be conducted, and we will (10) implement our dissemination plan which includes developing an implementation protocol that will provide guidance on how to implement OTQ. We will leverage existing partnerships and infrastructures such as the NYSSQL, NYC Treats Tobacco (NYCTT) and PCIP to disseminate the protocol. The findings have high potential for scale up and dissemination given the additional resources available through the state funded NYCTT also led by Dr. Shelley. After completion of the project we will be able to leverage NYCTT resources to provide onsite TA to other FQHCs and health care sites to effectively implement OTQ based on lessons learned from this project. Of note, URAM and BCHC would be the first sites in NYC to implement the OTQ program.

**c. Evaluation Design:**

**i. Metrics:** We will use RE-AIM (reach, effectiveness, adoption, implementation and maintenance) as the framework for our evaluation. The evaluation emphasizes both process and outcome measures to ensure that we are able to assess both if the intervention worked and why it worked (i.e. What were the processes needed to implement OTQ). *Table 4* shows the measures and data collection plans. We acknowledge that for this project there is overlap in the definition of the RE-AIM metrics. To assess the primary outcome, increased referrals to the NYSSQL, we will conduct a quasi-experimental single-arm, pretest-posttest study. As a

comparison we will obtain data from the NYSSQL on referrals from comparable FQHCs who have not implemented the OTQ program.

Secondary outcomes include the percentage of patients referred who were contacted by the NYSSQL, the rate of patient quit attempts and smoking abstinence (assessed via surveys conducted by the NYSSQL); and provider rates of tobacco screening, cessation assistance (brief counseling and/or prescribing medication). Provider adherence to the TDT guidelines (i.e., screening and assistance) will be obtained from the EHR.

*Table 4. Evaluation measures.* Effectiveness will measure the impact of the intervention on both primary and secondary outcomes. Primary outcomes will be assessed by the percentage of smokers referred to the NYSSQL among intervention FQHCs as compared to FQHCs who have not implemented the OTQ program; and the percentage of smokers who connect with a NYSSQL counselor among smokers referred. Secondary outcomes include the rate of patient quit attempts and smoking abstinence, as indicated by the number of patients from intervention FQHCs who connected with a NYSSQL counselor who report stopping use of tobacco for 24 hours or longer because they were trying to quit (quit attempt) and/or not smoking for the last seven days (smoking abstinence) among all patients connected to the NYSSQL from intervention FQHCs at three months post-intervention; and provider adherence to TDT guidelines, as indicated by the percentage of patients screened for tobacco use; and the percentage of smokers offered cessation assistance (defined as brief counseling and/or pharmacotherapy). Reach, which refers to the extent to which the program attracts a large and representative percentage of the target population, will be measured by representativeness of patients referred to the NYSSQL, as indicated by patient demographics and characteristics (i.e. gender, age, education, race/ethnicity, etc.); and the percentage of smokers referred that were successfully reached by the NYSSQL. Adoption will be assessed by the extent to which the FQHCs complete the steps for OTQ adoption, including implementing changes to the EHR, a new clinical pathway, a new TDT policy, etc. Implementation will be assessed by the percentage of patients screened for tobacco use; and the percentage of smokers offered cessation assistance. Maintenance will be measured by the percentage of smokers referred to the NYSSQL at one year after the end of the project. This evaluation will also assess process measures including, the percentage of providers that attended the trainings; number of technical assistance meetings and staff who attended; type of staff required for changes in EHR and other IT needs (i.e. IT personnel) and time spent by staff making the IT changes; other resources utilized; number of Plan-Do-Study-Act (PDSA) cycles and staff involved; and OTQ implementation barriers and facilitators. Lastly, the evaluation will assess the policy environment, as indicated by the status on federal policies (i.e. Meaningful Use and Patient-Centered Medical Home); involvement in national and statewide QI initiatives; and involvement in tobacco related QI initiatives.



<b>Table 4. Evaluation Measures</b>			
<b>Variable</b>		<b>Measure</b>	<b>Data source</b>
<i>Effectiveness</i>	Primary Outcomes	Referrals to the quitline and % of smokers who connect with a NYSSQL counselor	NYSSQL, health system EHR, and patient level surveys
	Secondary Outcomes	Rate of patient quit attempts, smoking abstinence, and provider adherence to TDT guidelines (i.e. screening and assistance)	
<i>Reach</i>		Representativeness of patients referred to NYSSQL, % of smokers referred that were reached by the NYSSQL	NYSSQL, and health system EHR
<i>Adoption</i>		To what extent did the FQHC complete the steps for adoption (changed EHR, new clinical pathway created, new policy etc.)	Qualitative interviews
<i>Implementation</i>		% patient screened for tobacco use % offered cessation assistance (defined as brief counseling and/or pharmacotherapy)	Health system EHR
<i>Maintenance</i>		% smokers referred to NYSSQL at 1 year after end of project	NYSSQL, and health system EHR
<i>Process measures</i>		% Providers attended trainings, number of technical assistance meetings and staff who attended, type of staff required for changes in EHR and other IT needs (i.e. IT personnel), and time spent by staff making the IT changes, other resources, number of PDSA cycles and staff involved, implementation barriers and facilitators.	Qualitative interviews and tracking system
<i>Policy environment</i>		Status on federal policies (meaningful use, PCMH status), involvement in national and statewide QI initiatives, and involvement in tobacco related QI initiatives.	Survey of FQHC Medical Directors

**Sources of Data:** As outlined in Table 4, data for the evaluation will be collected from five main sources: (1) NYSSQL database, (2) EHR data, (3) tracking system, (4) surveys, and (5) qualitative interviews. (1) The NYSSQL secure web-services database contains data that will be extracted for data analysis. The database collects a depository of data automatically transferred from the FQHC’s EHR (i.e. percentage of smokers referred to the NYSSQL), as well as, holds aggregate results on the percentage of patients successfully reached by the NYSSQL. (2) Data pulled from the FQHCs’ EHR system will include provider adherence to the TDT guidelines (i.e. screening and assistance). (3) A tracking system maintained by NYUSOM will capture ongoing process measures (i.e. percentage of providers attended the training, number of technical assistance meetings, etc.) (4) Survey data will be collected from both patients and the Medical Director of each FQHC. The patient survey will be administered to all patients from FQHC sites enrolled in the NYSSQL at three months post-enrollment and will ask about quit attempts and smoking abstinence. The Medical Director of each FQHC will also complete a baseline survey that will be composed of questions on site characteristics including staffing, workflow, IT expertise, current systems for screening and documenting TDT, current systems for referring patients to the NYSSQL and updated TDT quality measures obtained from the EHR. They will also be asked to complete questions to assess factors that may influence adoption and implementation of TDT guidelines (implementation climate, organizational readiness, and outcome expectancies), as well as, questions assessing the current policy environment (i.e. status on federal policies). (5)

Qualitative interviews will be conducted with the QI team and Medical Director of each site to assess barriers and facilitators to OTQ implementation, and the extent to which the FQHC completed the steps for adoption.

**Data Collection:** Data from the NYSSQL secure web-services database will be maintained and pulled by the NYSSQL. All data collected through the FQHCs' EHR system will be pulled by each FQHC's QI team, who will be trained and assisted by PCIP, accordingly. A tracking system maintained by NYUSOM project staff will be organized in both Microsoft Excel and REDCap (Research Electronic Data Capture) and will be retrieved from other sources such as meeting minutes, informal discussions, and tracking sheets. Patient surveys will be integrated into the NYSSQL's current evaluation program and therefore is an in-kind contribution. Patients will be contacted three months after their initial contact with the quitline by a member of the NYSSQL evaluation team to complete the follow-up survey. If patient cannot be reached after five call attempts, a paper-based survey will be mailed to the patient, also an in-kind contribution as this already part of NYSSQL's current evaluation program. The survey will take about three-five minutes to complete. Medical Director surveys will be administered by NYUSOM project staff. The Medical Director will be asked to complete an electronic survey via REDCap. Qualitative interviews will be conducted by trained NYUSOM project staff who will use a semi-structured guide to facilitate the interview. All participants will sign an informed consent form that indicates that all interviews are confidential, voluntary, and participants can withdraw at any time. With permission, interviews will be audio recorded to ensure more accurate data capture and transcription. The interviewer will also take notes throughout the duration of the interview to supplement the audio recording.

**Data Analysis:** Quantitative data will be analyzed in IBM Statistics v19 (SPSS Inc., Chicago, Illinois 2010) and qualitative data will be analyzed in ATLAS.ti. Descriptive statistics will be calculated for continuous variables and frequencies will be calculated for categorical variables. Bivariate analyses will be used to compare demographic variables (i.e. race/ethnicity, education level) of patients who are reached by the NYSSQL as compared to those who are not reached.

The primary outcome of the change in the percentage of smokers referred to the NYSSQL six months post-intervention (OTQ) as compared to baseline (traditional RTQ) will be analyzed among intervention FQHCs as compared to comparable FQHCs that have not implemented OTQ. Comparable FQHCs will be matched based on site characteristics (i.e. size, patient population served, etc.). A chi square test will be used to analyze the difference in NYSSQL referral rates between groups, and to assess the difference in the percentage of patients who connect with a NYSSQL counselor.

To analyze the secondary outcome of the change in provider adherence to TDT guidelines (i.e. percentage of patients screened for tobacco use, percentages of smokers offered cessation assistance) from baseline to six months post-intervention, a chi square test will be used. A chi square test will also be used to analyze the rate of patient quit attempts and smoking abstinence three months post-intervention, as compared to baseline.

For qualitative data, 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.<sup>xv xvi xvii</sup> We will use ATLAS.ti, a qualitative data analysis management software program. 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. The coding team will then 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.

**ii. Expected Amount of Change:** Based on previous studies of integrating an electronic referral system we expect a nearly 20-fold increase in the percentage of patients who connect with a telephone counselor at the quitline compared to providing referral cards and asking smokers to call on their own (current standard care).<sup>vii</sup> We also expect at least a 10-fold increase in number of referrals to the quitline.<sup>vii</sup> The proposed project is expected to impact patient-level outcomes by increasing smoking quit attempt and cessation abstinence rates among patients who enroll in NYSSQL services. We predict that after three months, there will be an approximate 60% quit attempt rate (defined as percentage of smokers who quit for at least 24 hours). We anticipate an abstinence rate (defined as percentage of smokers who report not smoking for the last 7 days) to be approximately 20% after three months.<sup>i xviii</sup>

**iii. Audience Engagement in the Project:** Patient engagement in the project will be indicated by the number of patients who were referred to the NYSSQL who were successfully contacted after five call attempts by the NYSSQL coach among total number of patients referred. Provider engagement in the project will be indicated by the number of clinical staff who was trained on TDT best practices among all clinical staff and the secondary outcome measures. Organizational engagement in the project will be indicated by the extent to which the FQHCs completed the steps for OTQ adoption.

**iv. Dissemination Plan:** Use and dissemination of the evaluation findings will persist throughout the duration of the project and stakeholders will be involved in its iterative and cyclical process. Findings from the proposed project will be disseminated to the various stakeholders (i.e. FQHC staff and providers and NYCTT partnering health care systems) through multiple communication channels and processes, respectively. Findings will be disseminated to partners in the form of a summary report and an implementation protocol (or how to manual) disseminated via the NYSSQL, NYCTT and PCIP websites, NYCTT and PCIP webinars, newsletters, and at NYSDOH state-wide Tobacco Control Program meetings. FQHCs will be encouraged to garner earned media by distributing an OTQ press release through various internal and external (local NYC) media venues in order to reach an even broader audience. Project staff will also submit findings for publication in relevant academic journals. Lastly, findings from both the process and outcome evaluation will be submitted to the National Cancer Institute's "Research-Tested Intervention Programs," which is a searchable database of cancer control interventions and program materials that are aimed to facilitate dissemination and adoption of evidence-based interventions.<sup>xix</sup>

**5. Detailed Workplan & Deliverables schedule: Year 1:** The first component of the year one project plan includes (1) assessing both FQHCs full site characteristics and obtaining updated TDT quality measures extracted from the EHR. The full site characteristic assessment will include information such as but not limited to; size of the FQHC, aggregate level patient demographics, comprehensive list of services the FQHC provided (i.e. behavioral health, HIV,

dental, housing, etc.), identification of NYS and/or federal regulatory reporting requirements and standards (i.e. is the site patient center medical home certified, or does it meet criteria for meaningful use?), and identifying other QI initiatives the FQHCs are engaging in. A thorough analysis of both FQHC's EHR's will be conducted by PCIP. The project staff will identify current TDT practices in the EHR including but not limited to: examining where in the EHR tobacco treatment is recorded and frequency, if there is a tobacco use screening system that cues to prompt providers to ask about smoking status, advise patients to quit and offer treatment, and establish if they have incorporated a "clinical extender" strategy including a system to refer patients to the NYSSQL. With PCIP's assistance, project staff will analyze current data from both FQHCs EHRs to assess the current compliance with PHS guideline-recommended care; including ensuring that all patients are screened for tobacco use, offered evidence-based treatment, and that these activities are documented in the EHR.

Although initial data was collected via NYUSOM pilot study (Table 3), it is known that both FQHCs have expanded services since, making the 2012 data an underrepresentation of NYC population served. The specific measures that will be collected include: percent of patients screen for tobacco use, percent of patients identified as smokers (have smoked in the past 30 days), percent of patients who received tobacco cessation counseling, percent of patients who were ready to quit/cut down tobacco use, percent of patients who receive a tobacco cessation prescription (tobacco cessation medication or NRT), and number of patients who received a referral to the NYSSQL as demonstrated through their EHR. This aggregate site-level data will be captured prior to the implementation of OTQ. Demonstrated through previous experiences partnering with FQHCs the site-level performance feedback findings are often surprising to HCO leadership who generally overestimate their organization's adherence to the guidelines. Thus it is important to show HCO leadership the TDT quality indicators so gaps in compliance with the PHS Guidelines can be identified.

Once baseline and site characteristics are identified (2) a QI team at each FQHC will be formed if not already in existence to meet regularly with project staff. A collaborative learning group will also be formed. Adapted from the Institute for Healthcare Improvement (IHI), the QI team will include at least one member who has the following roles: *clinical leadership* to test and assist in understanding how the referral adoption will affect the providers current workflow; *technical expertise* for this project will be in the form of an IT specialist as they will be responsible for programming and implementing the automatic EHR referral process; *day-to-day leadership* to lead the QI team in ensuring they are following the designated implementation timeline as well as meeting project deliverables; and *project sponsorship* to intervene with senior leadership if, and when implementation barriers occur.<sup>xx</sup> Project staff will provide additional assistance in clearly identifying roles and responsibilities of the QI team members to ensure accountability and effective OTQ implementation within both FQHCs.<sup>xxi</sup> Specific tasks will be designated such as but not limited; responsibility for extracting TDT data from the EHR, compiling reports and registries, and communicating and informing all staff the system-wide referral updates that will be occurring with OTQ.

Prior to implementation of OTQ, it is critical to analyze both FQHCs current workflow maps<sup>xxii</sup> for referring patients to the NYSSQL, if a process exists. Project staff will outline the FQHCs current workflow process in detail, and delineate the roles and responsibilities of providers and staff during all points of the patient visit. This is a critically important component

of the TA process as the pathway defines each step in the delivery of evidence based TDT from the screening process to cessation assistance and follow-up (e.g. referral via OTQ). The visual depiction will be beneficial in assisting the FQHC QI team in discussing the (3) redesign referral process of implementing OTQ. Together the QI team will collaborate in redesigning the referral process to integrate OTQ. Adapted from AHRQ's The Practice Facilitation Handbook,<sup>xxiii</sup> the QI team will discuss key redesign reflection questions such as if a patient is uninterested in being referred through OTQ how often will this be reassessed?, and what skills are necessary for providers to perform each step of the new redesign?

In collaboration with the NYSSQL, the FQHC QI teams will be (4) making various EHR updates to incorporate all OTQ components. The QI team within each FQHC will firstly be responsible for creating an OTQ script that will be embedded into the EHR. This script will assist the providers in ensuring the pertinent and simplistic consent information regarding OTQ is communicated appropriately to all patients while aligning with HIPAA standards. The script can be tailored to best fit the FQHCs mission, and will be directly embedded into the EHR referral screen. Secondly, with PCIP's and the NYSSQL's assistance the FQHC EHRs will be updated to have the capability, operability and functionality to send an automatic bidirectional referral. The NYSSQL will be providing various forms of TA including but not limited to: providing the full data exchange programming specification manual to both FQHC IT experts to ensure that the automatic data transfer is securely transmitted; NYSSQL IT specialist will schedule as needed conference calls, and web conferences to both FQHC sites to oversee that minimal complications and barriers exist in updating the EHRs to reflect the OTQ data exchange process; pilot test the OTQ referral process prior to launching it throughout the entire FQHC to ensure EHR test patient referrals are being tracked and communicated directly to the NYSSQL as planned; ensuring the FQHCs are receiving automatic test patient activity results via the EHR; and providing ongoing quality assurance monitoring.

As OTQ is a system level change, it is imperative the FQHC's current (5) policies and procedures manuals are updated to reflect the new referral process. Project staff will provide TA with these updates. In aligning with the 2008 PHS guidelines there are a variety of benefits in adapting a written TDT policy, as it allocates accountability to provide consistent and effective best practice TDT to all tobacco users. Policy drives practice, and as such, over the past 10 year's policy adoption has been a key component of NYUSOM's efforts to improve TDT across partnering HCOs. Through these previous experiences Medical Directors have expressed that implementing a TDT policy created a positive culture change within their organization as tobacco was now recognized as a priority, aided with expectations if there was staff turnover, and has helped assist in meeting regulatory standards. The organizational policy will reflect the full-spectrum best-practices for TDT, and include key components of the PHS guidelines such as, a detailed outline of the redesigned OTQ clinical workflow process, a sustainable approach that ensures clinicians have sufficient training on best practices, and a clearly identified implementation process to ensure that providers are given feedback regarding their performance, in addition to outline any additional necessary details regarding the OTQ referral system protocol.<sup>xxiv</sup> Once the policy is adopted and approved by the necessary senior leadership it will then be disseminated and communicated to all staff and providers, a step that is often neglected rendering the policy ineffective. Dissemination can take many forms such email

blasts to all staff and providers, newsletters, announcements at morning huddles, and incorporating a discussion of the new policy in all staff and provider trainings and orientations.

Additional TA will include (6) implementing a training curriculum to ensure the PHS guideline system strategy 2: system-level provision of staff training and cessation resources is addressed within both FQHCs. The training curriculum will be comprised of three components (A, B, C) as follows. Training component A includes an in-person training to all FQHC clinical staff that will review PHS guidelines best-practices, pharmacotherapy, and introduce the new policy along with screenshots demonstrating the full OTQ integration. Staff will have the opportunity to ask questions regarding the system-change. Project staff will conduct in-person trainings on two separate days to ensure that all providers attend. The training will be recorded, and disseminated to all staff post-training to use as a reference. Training Component B will consist of identifying site leaders (does not have to be QI team members) to train as designated as “site champions”/in-house TDT coordinators. Using a pre-existing train-the-trainer (TTT) model the TDT coordinators will increase their tobacco control-related knowledge and skills and be responsible for communicating and presenting this knowledge to future FQHC staff. The TTT model combines didactic sessions with case-based learning using “standardized practice” exercises, role-playing, and field experiences. Designating and training TDT coordinators will ensure a sustainable model is implemented. The TTT model will also build capacity among coordinators and site champions to implement the system strategies by focusing on QI and change management techniques. Training component C will ensure the QI team is appropriately trained on extracting data from the EHR as this is a necessity for creating smoker registries, generating reports, and demonstrating quality improvements. As experienced in EHR data extraction PCIP will provide assistance in conducting this training. Additionally, project staff will ensure that OTQ cessation resources are readily available at both FQHCs. This project plan will solely use existing patient-level materials developed by the NYSSQL, explaining how OTQ works. Ordering these materials is free of cost and they will be distributed to all patients who have screened yes for tobacco use.

After the trainings are complete, and the NYSSQL has confirmed with the FQHCs that no IT glitches are presently occurring in the automated data transfer via the EHR, then the (7) OTQ referral process will be launched and the OTQ referral process will be live for providers to use. The “go live” date will be disseminated to all staff at the FQHCs via multiple strategies to ensure all providers are aware of this important date.

Over the course of year one, the project staff in conjunction with the designated QI team at each FQHC will be conducting PDSA cycles with PCIP’s assistance. Derived from the most commonly used QI approach the Model for Improvement, PDSA cycles are essential in testing small change effectiveness.<sup>xvii</sup> Project staff will provide TA to FQHC QI teams who may not be familiar with the purpose of PDSA cycles or how to conduct them. Although the PDSA cycles included in this project plan will be TDT focused, it is believed that with some encouragement the FQHCs can use the PDSA cycle discipline to implement additional QI strategies in the future as they will already have the knowledgebase, tools, and TDT examples. Conducting PDSA cycles will create a culture within the FQHCs that values the effects of improvement strategies, and will also assist in keeping the project plan on track. As research has demonstrated PDSA cycles should be tested on a small scale first, the project plan will

incorporate this philosophy and test consecutive PDSA cycles before implementing the outlined above intervention strategies throughout the entire FQHC.<sup>xxv</sup>

Evaluation activities help with the identification of the extent to which the program outcomes are realized. Thus, a thorough (8) tracking system will be maintained that will collect various process measures. The process measures outlined in Table 4 will include program monitoring such as, tracking, documenting, describing and summarizing the characteristics of the implemented OTQ activities to inform the step-by-step protocol.<sup>xxv</sup>

**Year 2:** During year two an (9) evaluation will be conducted to assess the effectiveness of implementing OTQ within both FQHCs. The evaluation will demonstrate if the project plan goals were successful. The detailed outcome evaluation strategy can be found aforementioned above in the evaluation design section. The PDSA cycles, process measures and full evaluation design elements will inform the (10) development and dissemination of an easily adoptable best practices step-by-step OTQ implementation protocol. The purpose of this protocol is to serve as an exemplary model for other organizations to understand the different processes that go into the implementation of OTQ. This protocol will have an extreme level of detail including, but not limited to items such as time required, intended audience, suitable setting, and additional resources required. This resource will offer other potential interested FQHCs the opportunity to review the implementation process as well as assist in mitigating potential future barriers. This protocol will be disseminated via the various dissemination strategies as outlined above in the evaluation section (iv. Dissemination Plan).

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5. Table format of Workplan Deliverables and Schedule for Completion

TIMELINE NOTE: ♦ = Milestone	Year 1				Year 2			
	3	6	9	12	15	18	21	24
<b>Start up</b>								
1. IRB application submitted/approved	♦							
2. Finalize survey and tracking system	♦							
<b>Project Implementation</b>								
3. FQHC baseline assessment								
4. Form a QI team at each FQHC, and a collaborative learning group								
5. Analyze current referral workflow and redesign to incorporate OTQ implementation								
6. Update EHR to incorporate OTQ components and automatic data transfer				♦				
7. Update policy and procedure manual to reflect OTQ referral process				♦				
8. Provide technical assistance in the form of trainings								
9. Test data sharing process between NYSSQL and FQHCs								
10. Launch OTQ within URAM and BCHC				♦				
<b>Evaluation</b>								
11. Extract data from NYSSQL database and both FQHC's EHR (6 months post implementation)								
12. Administer patient surveys (3 months post enrollment in NYSSQL)								
13. Analyze extracted NYSSQL and FQHC EHR data (6 months post implementation)								
14. Analyze patient surveys								
15. Conduct qualitative interviews								
16. Analyze qualitative interviews								
17. Extract data from NYSSQL database and both FQHC's EHR (12 months post implementation)								
18. Analyze extracted NYSSQL and FQHC EHR data (12 months post implementation)								
19. Develop OTQ implementation protocol								♦
20. Disseminate OTQ implementation protocol								♦