

# Hospital-based Patient Navigation to Promote Smoking Cessation: a pilot RCT

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Study Protocol and Detailed Statistical Plan

Clinicaltrials.gov Registration: NCT03452371

Boston University Medical Campus IRB Protocol Number: H-37040

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## 1 Protocol Summary

<b>Title:</b>	Hospital-based Patient Navigation to Promote Smoking Cessation: a pilot RCT
<b>Population:</b>	<p>Study population will include individuals (both men and women, all races and ethnicities) who meet inclusion criteria: (1) hospitalized smokers at BMC; (2) smoked at least 1 cigarette per day in the past month; (3) able to speak, read, and understand English; (4) able and willing to participate and provide informed consent; (5) has a primary care physician at Boston Medical Center; (6) at least 18 years of age; (7) must have plans to quit smoking; and (8) must have a working telephone.</p> <p>Sample size: 50</p>
<b>Intervention:</b>	3 hours of patient navigation over the next 3 months
<b>Objectives:</b>	To assess effect of patient navigation to promote smoking cessation
<b>Design/Methodology:</b>	<p><b>Enhanced Traditional Care:</b> Participants randomized to this group will receive a resource card that has information on quitlines, BMC's outpatient program number, and websites for smoking cessation.</p> <p><b>Patient Navigation Intervention:</b> We base our intervention on the Social Contextual Model, a multi-level approach to health education which stresses the influence of life experiences (e.g. stress and financial problems) and social relationships (e.g. social networks and family roles) on the practice of health behaviors.</p> <p><b>Intervention Components and Content.</b> Participants will meet the navigator in person if she is available, or will be introduced by telephone. Participants will receive navigation from a trained navigator, based centrally in the Section of General Internal Medicine. Our navigator has a BA degree, and has extensive experience doing community health outreach. Participants will receive up to ten hours of patient navigation, in person or over the phone, over a 3-month period. We chose a ten-hour intervention dose based on 1) a prior study of motivational interviewing in low-income smokers and 2) our prior work studying patient navigation to promote smoking cessation. We have not designated a specific number of contacts, but allot a maximum of ten hours of patient navigation time per participant. The navigator will work flexible hours, contacting patients on evenings and weekends as necessary. Patient navigation contacts will involve individual counseling to help the patient achieve abstinence from smoking. Navigators will also screen participants for social determinants of health which may be preventing them from quitting smoking, using an adapted version of a validated social determinants of health screening tool. Patient navigation intervention calls will use motivational interviewing (MI) strategies to do the following: (1) Assess stage of change for smoking cessation; (2) Assess and reinforce any prior abstinence from smoking and/or any efforts made to reduce or quit smoking; (3) Explore the patient's motivation to quit smoking, drawing on recent</p>

	illness, financial situation, and family situation as appropriate; advise about the risks of smoking and benefits of quitting (4) Discuss past experience with utilizing cessation support; (5) Explore potential barriers to using smoking cessation medications (e.g. lack of trust, cost, misconceptions about treatment (e.g. that nicotine replacement therapy (NRT) is more harmful than cigarettes)); (6) Brainstorm strategies to address identified barriers; (7) Elicit commitment to accept another patient navigation counseling call, discuss timing.
<b>Total Study Duration:</b>	3 months
<b>Subject Participation Duration:</b>	3 months

## 2 Background/Rationale & Purpose

Smoking cessation interventions are the ‘gold standard’ of healthcare cost effectiveness because they achieve more life-years gained for fewer resources than other interventions. Although there are several effective, guideline-recommended cessation treatments, low-income and minority populations suffer a disproportionate burden of tobacco-related morbidity and mortality due to high smoking rates, lack of access to cessation services, and lack of support for quitting. Hospitalization presents an opportunity to reach smokers who otherwise may not seek tobacco treatment. It offers a ‘teachable moment’ during which the risks of smoking are highlighted, leaving smokers more receptive to cessation interventions. Highly intensive counseling interventions that begin during the hospital stay *and continue with supportive contacts* for at least one month after discharge increase smoking cessation rates post-hospitalization by 40%, among patients hospitalized at non safety-net hospitals. However, we are unaware of interventions for hospitalized smokers that are effective among minority and low SES smokers hospitalized at safety-net hospitals. In a recent RCT (in press at *JAMA Internal Medicine*),<sup>1</sup> we demonstrated that patient navigation and financial incentives substantially increased biochemically confirmed smoking cessation at 12 months among minority and low-SES primary care smokers. Patient navigation<sup>1,2</sup> is a low-cost approach in which a community member trained in motivational interviewing (MI) assesses barriers to accessing evidence-based tobacco treatment, and addresses underlying social determinants of health. While the intervention improved quit rates in the ambulatory setting, we have not tested the efficacy of the patient navigation intervention component among recently hospitalized smokers. By implementing the intervention among recently hospitalized smokers (who may be more motivated to quit smoking), we will increase the proportion of participants that receive the minimum intervention dose from the navigator. We propose to pilot-test patient navigation among recently hospitalized smokers in preparation for a larger randomized trial. We propose the following **specific aims**:

**Aim 1. To adapt our previously developed patient navigation primary care-based smoking cessation intervention into a scalable intervention delivered to recently hospitalized smokers at a large urban safety-net hospital.** We propose to add screening and referral for social determinants of health using a validated screening tool<sup>3</sup> embedded into the navigator script. We will tailor the navigator role to the population of recently-hospitalized smokers, mapping to theoretical constructs of the Social Contextual Model.<sup>4</sup>

**Aim 2. To determine the acceptability and feasibility of the adapted patient navigation smoking cessation intervention by pilot-testing it among 25 smokers at a large urban safety-net hospital.**

## 3 Objectives

### 3.1 Study Outcome Measures

Primary Outcome: whether a prescription for an FDA-approved smoking cessation medication was sent to the participants’ pharmacy (Y/N, based on chart review)

Secondary outcomes: Self-reported smoking cessation at 3 months, utilization of smoking cessation medication, stage of change<sup>8</sup> assessed at baseline and 3 months, according to the following categories: pre-contemplation, contemplation, preparation, or action. For each participant, we compare stage of change at baseline vs. 3 months. We will also measure

level of nicotine dependence (baseline and 3 months), measured by the Fagerstrom Test for Nicotine Dependence,<sup>9</sup> and use of other tobacco treatment support (3 months), defined as self-report of all tobacco treatment support received, including support from non-study sources, including the internet, during the 3-month study period.

## 4 Study Design

Study Site: We will recruit 50 hospitalized adults at Boston Medical Center (BMC).

Inclusion Criteria: age  $\geq 18$ , English-speaking, Medicaid-insured, hospitalized on the general internal medicine or family medicine service and have a primary care provider at BMC; smoked  $\geq 1$  cigarettes/day in the past month; when asked, “What is your plan about smoking after you leave the hospital?” response is either: “I plan to stay quit when I leave the hospital,” or “I plan to try to stay quit when I leave the hospital.”

Exclusion Criteria: no telephone; expected hospital stay of  $< 24$  hours; cannot give informed consent or participate in counseling due to psychiatric or cognitive impairment or communication barrier; admitted to surgical, obstetric or psychiatric units; estimated life expectancy of  $< 12$  months; or medical instability.

Identification of potential participants: An EPIC programmer who works with the Inpatient Tobacco Treatment Program will identify potential participants using EHR data each week.

Recruitment, screening and consent procedures: Utilizing a daily roster of English-speaking hospitalized smokers, a trained research assistant will screen patients for study eligibility, obtain informed consent, conduct the baseline assessment, and randomly assign patients to study condition. Participants will receive a \$15 gift card for completing the baseline assessment. We estimate that we can recruit 4-5 patients per week, over 12 weeks.

Randomization Procedure: *All participants will receive inpatient tobacco cessation counseling.* We will randomize participants to one of two treatment arms: (1) ETC, where participants are referred at discharge to a quit line or outpatient smoking cessation group; or (2) PN: a patient navigator to coordinate tobacco treatment with the smoker’s outpatient healthcare team and address any underlying social determinants of health that are barriers to cessation (identified using a validated social determinants of health screening tool).

Eligible patients who are interested in the study and provide informed consent will be randomized and informed of the randomization assignment by the research assistant. We will stratify randomization by participants’ response regarding their plan to quit smoking (“I plan to stay quit” or “I plan to try to stay quit”). A computer-generated sequence of random numbers will assign treatment groups.

Data Collection: We will collect data by phone at 3 months post-randomization.

Retention: We expect to retain at least 60% of participants from baseline to 1-month follow-up, based on our prior experience conducting assessments at 3 (70% retention) and 6 months (76% retention) in similar populations.<sup>1,2</sup> To maximize retention we will collect contact information including home address, phone, cell phone, beeper, e-mail, and phone numbers of three contacts. We will provide \$20 for completion of the 1-month assessment.

Patient Navigation Intervention: We base our intervention on the Social Contextual Model,<sup>4</sup> a multi-level approach to health education which stresses the influence of life experiences (e.g. stress and financial problems) and social relationships (e.g. social networks and family roles) on the practice of health behaviors.

Participants will meet the navigator in person if she is available, or will be introduced by telephone. Participants will receive navigation from a trained navigator, based centrally in the Section of General Internal Medicine. The navigator has a BA degree, has extensive experience doing community health outreach, and has previously completed the University of Massachusetts “Basic Skills for Working with Smokers Online Course.”<sup>5</sup> Participants will receive up to ten hours of patient navigation, in person or over the phone, over a one-month period. We chose a two-hour intervention dose based on 1) a prior study of MI in low-income smokers<sup>6</sup> and 2) our prior work studying navigation to promote smoking cessation. We have not designated a specific number of contacts, but allot a maximum of ten hours of patient navigation time per participant. The navigator will work flexible hours, contacting patients on evenings and weekends as necessary. Patient navigation contacts will involve individual counseling to help the patient achieve abstinence. We will adapt and incorporate into the PN script a modified version of the WE CARE Survey, which consists of 12 questions designed to: (1) identify six unmet material needs (inadequate education, employment, food security, housing, childcare, and household heat) by self-report (e.g., Are you employed?) and 2) determine whether participants would like assistance with each problem (e.g., If No, do you want help?). The survey takes less than five minutes to complete and has a test-retest reliability of 0.92.<sup>7</sup> Thus, navigators will screen participants for social determinants of health which

may be preventing them from quitting smoking. Patient navigation intervention calls will use MI strategies to: (1) Assess stage of change for smoking cessation; (2) Assess/reinforce prior abstinence from smoking and/or efforts made to reduce/quit smoking; (3) Explore patient's motivation to quit, drawing on recent illness, financial situation, and family situation as appropriate; advise about the risks of smoking/benefits of quitting (4) Discuss past experience with utilizing cessation support; (5) Explore potential barriers to using smoking cessation medications (e.g. lack of trust, cost, misconceptions about treatment (e.g. that nicotine replacement therapy (NRT) is more harmful than cigarettes)); (6) Brainstorm strategies to address identified barriers; (7) Elicit commitment to accept another patient navigation counseling call, discuss timing.

Minimum navigation intervention dose: completion of MI calling script with the navigator

Navigator Training and Evaluation. We will train the navigator in issues of relevance to recently hospitalized patients (e.g. how to make follow-up appointments and assist with issues that arise with post-discharge medications). We will also train the navigator in tobacco treatment and barriers to treatment engagement among poor/minority patients (including how to screen for/address social determinants of health). The BNI-ART Institute at the BU School of Public Health will deliver a standard, validated MI booster training program. This training will occur over a half-day and focus on reviewing MI skills and delivery of the intervention. MI skills will be reviewed through didactics, demonstrations, role-plays, and video. The navigator will be evaluated on both process (helpfulness, warmth, empathy), and content (intervention adherence). Following training, Dr. Lasser will meet weekly with the navigator to ensure skill maintenance by reviewing audiotapes of intervention calls and providing corrective feedback.

Preserving Internal Validity/Treatment Fidelity, and Program Tracking. The intervention is manual-based. After each patient interaction, the navigator will complete a checklist of intervention components that were delivered. We will use these checklists to ensure that the intervention is delivered as intended, and to estimate intervention "dose" and treatment exposure. We will audiotape 5 participant interactions with permission from the participant; Dr. Lasser will monitor tapes for protocol adherence.

Evaluation Design and Measurement.

Assessments. Participants will complete assessments at baseline and one month. A blinded, trained research assistant will administer assessments at the bedside (baseline) and over the telephone (1-month). The assessments require under 30 minutes to complete. Subjects will receive an incentive of \$20 for completion of the 1-month assessments. The PI will also conduct an in-depth interview with the patient navigator to explore barriers to successful navigation.

Primary Outcome: whether a prescription for an FDA-approved smoking cessation medication was sent to the participants' pharmacy (Y/N, based on chart review)

Secondary outcomes: Self-reported smoking cessation at 3 months, utilization of smoking cessation medication, stage of change<sup>8</sup> assessed at baseline and 3 months, according to the following categories: pre-contemplation, contemplation, preparation, or action. For each participant, we compare stage of change at baseline vs. 3 months. We will also measure level of nicotine dependence (baseline and 3 months), measured by the Fagerstrom Test for Nicotine Dependence,<sup>9</sup> and use of other tobacco treatment support (3 months), defined as self-report of all tobacco treatment support received, including support from non-study sources, including the internet, during the 1-month study period.

## **5 Potential Risks and Benefits**

### **5.1 Risks**

(1) Loss of confidentiality: To minimize the risk of loss of confidentiality, the study coordinator will collect all data, and the study coordinator, data manager, and PI will be the only members of the team with access to the link between unique identifiers and patient data. The key will be stored on an encrypted server behind the university's firewall. Data will be stored on a secure server to which only designated individuals have access, thus providing a secure environment for all project data. The database will be backed up on a nightly basis. Any hard copy materials will be kept in a locked file in the PI's locked office. Any research staff who has access to patient health information will be trained in human subject's research that includes how to keep this kind of information private. Results will never be presented in any way where a patient could be identified.

(2) Participant discomfort in answering sensitive questions: The surveys may ask some questions that are sensitive to the study participant. The participant will be told that he/she may refuse to answer any or all questions, and that refusal to

answer a question will not affect his/her medical care and will not keep him/her from participating in the rest of the study.

(3) Potential unknown risk: There may be unknown risks/discomforts involved. Study staff will update participant in a timely way on any new information that may affect their health, welfare, or decision to stay in this study.

## **5.2 Potential Benefits**

This research is being conducted with the primary goal of producing knowledge, and so the primary benefits to be gained are those related to the knowledge that the research may produce. An accurate understanding of the effects of this intervention on improving access to smoking cessation programs and leading to smoking cessation itself is crucial in reducing disparities.

## **5.3 Analysis of Risks in Relation to Benefits**

In light of the tremendous benefits to public health and individual smokers of developing more effective smoking cessation programs, as well as our efforts, outlined above, to mitigate all risks associated with this study, we believe that this study presents a highly favorable risk-benefit ratio for participation.

# **6 Study Subject Selection**

## **6.1 Subject Inclusion Criteria**

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

- 1) Hospitalized smokers at BMC
- 2) At least 18 years of age
- 3) Must smoke at least one cigarette per day in the past month
- 4) Able to speak, read, and understand English
- 5) Able and willing to comply with all study protocols and procedures
- 6) Having a PCP in Boston Medical Center
- 7) Possession of a telephone (home or cell)
- 8) Must have plans to quit smoking

## **6.2 Subject Exclusion Criteria (See table 1)**

An individual who meets any of the following criteria will be excluded from participation in this study:

- 1) Cannot give informed consent or participate in counseling due to psychiatric or cognitive impairment or communication barrier
- 2) Medical instability
- 3) Estimated life expectancy of <12 months

# **7 Arms and Interventions**

## **7.1 Comparator Arm (*ENHANCED USUAL CARE*):**

Enhanced Traditional Care: Participants randomized to this group will receive a resource card that has information on quitlines, BMC's outpatient program number, and websites for smoking cessation.

## **7.2 Intervention Arm:**

Patient Navigation Intervention: We base our intervention on the Social Contextual Model, a multi-level approach to health education which stresses the influence of life experiences (e.g. stress and financial problems) and social relationships (e.g. social networks and family roles) on the practice of health behaviors.

Intervention Components and Content. Participants will meet the navigator in person if she is available, or will be introduced by telephone. Participants will receive navigation from a trained navigator, based centrally in the Section of General Internal Medicine. Our navigator has a BA degree, and has extensive experience doing community health outreach. Participants will receive up to ten hours of patient navigation, in person or over the phone, over a 3-month period. We chose a ten-hour intervention dose based on 1) a prior study of motivational interviewing in low-income smokers and 2) our prior work studying patient navigation to promote smoking cessation. We have not designated a specific number of contacts, but allot a maximum of ten hours of patient navigation time per participant. The navigator will work flexible hours, contacting patients on evenings and weekends as necessary. Patient navigation contacts will involve individual counseling to help the patient achieve abstinence from smoking. Navigators will also screen participants for social determinants of health which may be preventing them from quitting smoking, using an adapted version of a validated social determinants of health screening tool. Patient navigation intervention calls will use motivational interviewing (MI) strategies to do the following: (1) Assess stage of change for smoking cessation; (2) Assess and reinforce any prior abstinence from smoking and/or any efforts made to reduce or quit smoking; (3) Explore the patient's motivation to quit smoking, drawing on recent illness, financial situation, and family situation as appropriate; advise about the risks of smoking and benefits of quitting (4) Discuss past experience with utilizing cessation support; (5) Explore potential barriers to using smoking cessation medications (e.g. lack of trust, cost, misconceptions about treatment (e.g. that nicotine replacement therapy (NRT) is more harmful than cigarettes)); (6) Brainstorm strategies to address identified barriers; (7) Elicit commitment to accept another patient navigation counseling call, discuss timing.

## **8 Study Procedures**

### **8.1 Screening and Recruitment**

First, medical record (MR) will be accessed to determine (1) if patient is a current smoker (patients must be current smokers), (2) age of participant (must be age 18 or greater), (3) currently hospitalized on the general internal medicine or family medicine services or hospitalized within the past month, (4) have a primary care provider at BMC, (5) an estimated life expectancy of <12 months and (6) medical instability.

For patients that have not been excluded by MR review, the following questions will be asked to confirm eligibility:

How old are you? (must be  $\geq 18$ )

Are you a current smoker? (smoked at least 1 cigarette per day in the past month)

Do you have a working telephone? (must have working telephone)

Do you read, understand or speak English? (must read, understand, and speak English)

Are you able and willing to provide informed consent? (must be willing and able to provide informed consent)

When, if ever, do you plan to quit smoking cigarettes? (must have plans to quit smoking within 6 or more years)

The first contact could be made in-person prior to discharge, or over the phone, if patient has been discharged.

### **8.2 Consent Procedures**

In-person: The research assistant will approach potentially eligible participants and ask them if he /she can be asked a few screening questions. Subjects will be given at least several hours before they are discharged from the hospital to decide if they want to participate. After being found eligible, the research assistant will review the consent document with the potential participant. During the consenting process, she will describe the study and answer any questions the

participant may have. She will then ask all those who are willing to participate to sign the form. The consenting procedure will take place in a private exam room in the hospital.

Over the phone: If patients are discharged from the hospital, the Research Assistant will review the consent document with the potentially eligible participants over the phone. Following the consent document, she will describe the study and answer any questions the participant may have. If a person would like to think about it, they will be asked to contact us within 1 week if they are still interested in participating. If participant is interested in participating, the RA will mail participant two copies of the consent form with a prestamped envelope and have him or her mail back a signed version. No study procedures (except for screening) will occur prior to receiving the signed consent.

### **8.3 Randomization**

Randomization will occur after RA obtains informed consent from the participant. Participants will be randomly allocated in a 1:1 ratio to the intervention or comparator arm.

### **8.4 Assessments**

Participants will complete assessments at baseline and 3 months. A trained research assistant will administer these assessments either in-person or over the phone. The assessments require under 30 minutes to complete. Participants will receive an incentive of \$15 for completion of baseline assessment and \$20 for completion of the 3-month assessment.

### **8.5 Cost/payment**

There is no cost associated with participation in the study beyond any costs normally associated with the care the patients are receiving at BMC.

Participants will receive up to \$35 to thank them for participating in the study. Participants will receive a \$105 gift card for completing the baseline assessment and a \$20 gift card for completing the 3-month assessment.

## **9 Assessment of Safety and Data Safety Monitoring Plan (DSMP)**

This study is not greater than minimal risk. Unanticipated Problems, Adverse Events, and protocol deviations will be reported to the IRB as required by IRB policies (<http://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#6.6.3>).

The study monitor will be the Principal Investigator at Boston Medical Center/BU Medical Campus, and will report all adverse events and Unanticipated Problems to the IRB in compliance with IRB policy, Federal/State regulations, and sponsor requirements (as applicable).

## **10 Data Handling and Record Keeping**

### **10.1 Confidentiality**

All data files will be kept on a HIPAA-compliant secured shared drive with access restricted to project staff using password protected computers. Initially, research and medical records will be used to build the analytic databases. Each subject will be assigned a unique study identification number and all other identifiers will be removed as early as possible without compromising the conduct of the study. The linkage file between study identification number and medical record number will be stored separately on a password-protected server accessible only to the principal investigator, project manager and programmer/analyst. Confidentiality of patient information will be protected by using password-protected computers for all data analysis and management, as well as keeping confidential information printed on hard copies in locked file cabinets in the PI's locked office. Only project staff will have access to confidential



information and have been trained in compliance and working with protected health information. Study information will only be shared among project staff as needed to complete the study objectives using password-protected files on restricted-access secured shared drives.

## **10.2 Study Records Retention/Data and Safety Monitoring Plan**

### **Study Records Retention.**

Study data will be kept for seven years after the study is completed. Paper materials will then be shredded and files will be deleted from study computers.

- PHI and the key to what unique identifier goes with what medical record number will be destroyed at the earliest opportunity, no later than five years after publication of the results (in aggregate anonymous format).

### **Data and Safety Monitoring Plan.**

PI will be responsible for monitoring data and safety of all study participants. The Boston University IRB will oversee the process. The risks of this project are small, and the likelihood of significant adverse events is low. The following steps will be implemented to ensure data is secure:

- **Web Form/Data Security.** Information posted on forms will be electronically encrypted secure socket layering (SSL) encryption technology so that only the intended recipient can decode the data. Files stored on BUMC servers will be protected by electronic 'firewalls' that restrict access to designated users. This system utilizes unique login names and passwords and identifies the IP address of the user's computer. Data is stored on a secure server to which only designated individuals have access.
- **Database Infrastructure.** Access to the database will be implemented by means of unique login names and passwords. Data will be stored on a secure server to which only designated individuals have access. Database is backed up on a nightly basis.
- **Database Security.** Database security provided by BUMC OIT. Because the server will be part of the BUMC network NT domain, only connections from users authenticated from the domain controller are accepted, thus providing a secure environment for all Center data. The policy for computer systems security implemented at BUMC: (1) Provide physical security of data; and (2) Provide virtual security via connectivity.
- **Provide Security for Data.** All data are protected with disaster recovery via several methods: (1) Hardware redundancy; (2) Data backup, and (3) Data Security.

## **11 Statistical Plan**

### **11.1 Study Aims**

**Aim 1.** To adapt our previously developed patient navigation primary care-based smoking cessation intervention into a scalable intervention delivered to recently hospitalized smokers at a large urban safety-net hospital.

**Aim 2.** To determine the acceptability and feasibility of the adapted patient navigation hospital-based smoking cessation intervention by pilot testing it among 25 smokers at a large urban safety-net hospital.

### **11.2 Sample Size Determination**

The aim of this study is to determine the acceptability and feasibility of an adapted patient navigation smoking cessation intervention by pilot-testing it among 25 smokers at a large urban safety-net hospital. We will conduct a pilot RCT,

randomizing fifty hospitalized smokers to one of 2 study arms. We believe an n of 50 is the necessary sample size to determine acceptability and feasibility, and to have publishable results.

### 11.3 Statistical Methods

For categorical outcomes of engagement and self-report cessation, we plan to report percentages and 95% confidence intervals; for continuous outcomes we examine means, standard deviations, and ranges. In order to determine if the patient navigation condition achieves greater smoking cessation at 3-month follow-up compared to standardized inpatient counseling condition, we will compare groups using chi-square tests and note differences that are statistically significant at the  $\alpha < 0.05$  level. Analyses will be based on intent-to-treat.

We will use multiple logistic regression to control for potential confounders identified in bivariate analyses as well as variables of *a priori* clinical significance (gender, age, race/ethnicity). We will evaluate odds ratios with 95% confidence intervals to determine the relative magnitude of the adjusted association for each variable. Independent variables with strong correlations may result in collinearity. To address collinearity, we will construct separate models, each with one of the variables, and assess both the C statistic and the coefficients for the other variables in the model. Dropouts and missing data: We expect the majority of missing data to be due to dropouts due to moving or failure to remain in the study. We will investigate whether missing data is associated with patient characteristics. While data may not be missing completely at random, it may be reasonable to assume that data are missing at random. If this is the case, multiple imputations methods originally developed for sample survey data is applicable to clinical trials with dropouts and shown to be effective. Analytic software: We will use SAS version 9.4 (SAS Institute Inc, Cary, NC).

## 12 Ethics/Protection of Human Subjects

This study is to be conducted according to applicable US federal regulations and institutional policies (which are based in federal regulations, guidance, and ICH Good Clinical Practice guidelines).

This protocol and any amendments will be submitted to the Boston Medical Center and Boston University Medical Campus IRB, for formal approval of the study conduct. The decision of the IRB concerning the conduct of the study will be made in writing to the investigator. A copy of the initial IRB approval letter will be provided to the sponsor before commencement of this study.

All subjects for this study will be provided a consent form describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. The consent form will be submitted with the protocol for review and approval by the IRB. The consent of a subject, using the IRB-approved consent form, must be obtained before that subject is submitted to any study procedure. Consent will be documented as required by the IRB.

## 13 Literature References

1. Lasser K, Quintiliani L, Truong V, et al. Effect of patient navigation and financial incentives on smoking cessation among primary care patients at an urban safety-net hospital: a randomized controlled trial. *JAMA Intern Med*. In press
2. Lasser KE, Kenst KS, Quintiliani LM, et al. Patient navigation to promote smoking cessation among low-income primary care patients: a pilot randomized controlled trial. *J Ethn Subst Abuse*. 2013;12(4):374-390.
3. Kendzor DE, Businelle MS, Poonawalla IB, et al. Financial Incentives for Abstinence Among Socioeconomically Disadvantaged Individuals in Smoking Cessation Treatment. *Am. J. Public Health*. 2014;13:e1-e8.
4. Sorensen G, Barbeau E, Hunt MK, Emmons K. Reducing social disparities in tobacco use: a social-contextual model for reducing tobacco use among blue-collar workers. *Am. J. Public Health*. 2004;94(2):230-239.
5. UMASS Medical School Center for Tobacco Treatment Research and Training. Basic Skills for Working with Smokers - Online Course. 2017; [https://www.umassmed.edu/tobacco/training/basicskills\\_online/](https://www.umassmed.edu/tobacco/training/basicskills_online/).

6. Borrelli B, McQuaid EL, Novak SP, Hammond SK, Becker B. Motivating Latino caregivers of children with asthma to quit smoking: a randomized trial. *J. Consult. Clin. Psychol.* 2010;78(1):34-43.
7. Garg A, Butz AM, Dworkin PH, Lewis RA, Thompson RE, Serwint JR. Improving the management of family psychosocial problems at low-income children's well-child care visits: the WE CARE Project. *Pediatrics.* 2007;120(3):547-558.
8. Prochaska J, Redding C, Evers K. The Transtheoretical Model and Stages of Change. *Health Behavior and Health Education: Theory, Research, and Practice.* Glanz K, Lewis FM, Rimer BK, editors. San Francisco: Jossey-Bass; 1997.
9. Heatherton TF, Kozlowski LT, Frecker RC, Fagerstrom KO. The Fagerstrom Test for Nicotine Dependence - a Revision of the Fagerstrom Tolerance Questionnaire. *Br. J. Addict.* 1991;86(9):1119-1127.