Patient Navigation for Lung Screening at MGH Community Health Centers
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I. SPECIFIC AIMS

Specific Aim 1: To develop a patient navigator (PN) program for lung screening for patients who are current smokers, aged 55-77 years, potentially eligible for lung screening and are receiving care at community health centers (CHCs) affiliated with MGH.

Specific Aim 2: To evaluate the effectiveness of the new lung screening PN program in improving screening rates and increasing use of tobacco cessation services in a randomized controlled trial.

Specific Aim 3: To demonstrate that equity is maintained in rates of lung screening and in follow up of abnormal chest CT results, comparing eligible smokers from CHCs with eligible smokers from other practices within the MGH primary care network.

Specific Aim 4: To collect quantitative data about patient satisfaction with the navigators in the lung screening PN program

Specific Aim 5: To explore CHC primary care providers opinions about the lung screening PN program via survey

II. BACKGROUND AND SIGNIFICANCE

Though the incidence of lung cancer is similar to other common cancers such as breast and colorectal cancer, the large discrepancy in terms of mortality can be attributed in part to the widespread availability of screening and early detection for breast and colorectal cancer. The National Lung Screening Trial (NLST) sought to

evaluate screening using low-dose helical CT (LDCT) compared to chest radiography at baseline and then annually for 2 years. The study evaluated 53,439 asymptomatic participants, 55 to 74 years of age, with history of at least 30 pack years of smoking enrolled at 33 centers in the U.S. from August 2002 through April 2004. Initial results published in 2011 showed an increase in lung cancer diagnosed in participants in the LDCT group (292, 1.1%) compared with the radiography group (190, 0.7%).[1] Importantly, more early stage lung cancers were diagnosed in the LDCT group compared to the radiology group (158 versus 70) along with similar numbers of late-stage cancers in each group. Follow up of the participants through the end of 2009 showed statistically significant relative reduction in mortality from lung cancer with low-dose CT screening of 20%.[1, 2]

As a result of the NLST and prior lung cancer screening trials using LDCT,[3, 4] the U.S. Preventive Services Task Force (USPSTF) has issued new draft guideline recommendations.[4, 5] The proposed screening recommendations for LDCT apply to men and women smokers or former smokers who quit in the past 15 years, without signs or symptoms of lung cancer, between the ages of 55 and 80 years, who have a 30+ pack-years of smoking. In February of 2015 Medicare announced its requirements for LDCT screening. All high risk current and former smokers as defined by USPSTF, age 55-77 are eligible for annual LDCT. Additionally, patient must receive a written order for LDCT lung screening and shared decision making visit, furnished by a physician or qualified non-physician practitioner.[6]

The availability and coverage for LDCT screening does not mean that all eligible individuals will be screened. To improve cancer screening and follow-up in vulnerable populations, various strategies have been evaluated, including patient navigation.[7-9] Implemented in 1990 by Freeman, patient navigation (PN) uses culturally and linguistically tailored outreach workers to explore barriers to cancer care and navigate patients to obtain necessary care.[10] Several studies have shown that patient navigation can significantly improve breast and colon screening rates,[11-14] follow up after abnormal results[15-19] and decrease disparities in care.[20] Currently, lung screening with LDCT has not been widely used at Massachusetts General Hospital (MGH) As a result, we have a unique opportunity to investigate how to promote screening in eligible, vulnerable patients and to prevent the creation of disparities in care.

III. SUBJECT SELECTION

According to internal MGH data from 2012, 1480 patients aged 55-79 years at MGH CHCs were current smokers. Of these patients, 204 had a chest CT scan in the prior 18-months and/or had a diagnosis of lung cancer. Because of new Medicare guidelines we will only include patients that are aged 55-77 years and additionally exclude patients that providers deem ineligible for lung cancer screening. We estimate the total number of patients eligible for our interventions to be around 1200.Our experience in prior PN colorectal cancer screening interventions is that one full-time navigator assigned 400 patients will be able to reach/work with 300 patients over a 9-month period. Since our navigator will also follow-up abnormal CT results, our study will last one year. Eligible patients will be identified, randomized, and an electronic list of patients will be downloaded into an existing TopCare navigator data base. The navigators will use this system to track patients and interventions. Patients randomized to the interventions group will be recruited by navigators during their visits to the health center or over the phone. Since the navigator program is already standard of care at MGH, its expansion to include lung screening is considered part of usual care.

For Specific Aim 5, primary care physicians (PCPs) and nurse practitioners (NPs) from the community health centers with the PN program will be asked to complete a survey following the study period. There are approximately 81 PCPs and NPs who will be asked to complete the survey.

IV. SUBJECT ENROLLMENT

For this study, we will use a newly developed TopCare smoking and lung screening registry. The registry uses the data from patient's EMR regarding the smoking history and imaging (most recent chest CT) and it is daily

updated. We will choose the current smokers age 55-77 from the registry who did not have chest CT in the last year receiving care at MGH health centers. We will e-mail primary care providers a list of their patients and ask them to notify us in a week if they do not want us to contact a patient and to provide a reason why they believe patient is not eligible for lung screening. Patients meeting eligibility criteria for the study according to the criteria above will be identified and randomly assigned to navigation or control group. An electronic list of patients assigned to the intervention group will be downloaded into an existing TopCare navigator data base. The navigators will use this system to track patients and record interventions. Patients randomized to the intervention group will be recruited by navigators during their visits to the health center or over the phone. Since the navigator program is already standard of care at MGH, its expansion to include lung screening is considered part of usual care.

The patients in the intervention group will be mailed a letter about the program in English or Spanish with educational materials about lung screening following randomization and prior to any contact by the PN. A week later, the PN will contact patients over the phone or in person during office visits. For patients that speak languages other than English or Spanish, this initial contact with the PN will be aided by an interpreter. The interpreter will review the recruitment letter and Fact Sheet with the patient and ask the patient if they are interested in continuing with the research study. During this initial contact, the PN will obtain a detailed history to determine if the patient is eligible for lung screening. The PN will educate patients about lung screening and explore their barriers to screening. The PN will coordinate scheduling a shared decision appointment with a provider and, whenever feasible, attend the visit with the patient. The PN will further coordinate scheduling the lung screening test if the provider and patient made that decision and navigate the patient to obtain the test. Interventions may include: reminding the patient about the test, helping with translation, insurance issues, transportation, and overcoming any other system barriers as needed. After screening, PN will review the results. If the patient has an abnormal test result, the navigator will contact the patient's primary care physician and help the patient obtain required follow-up.

As a part of lung screening, the PN will assess the patient's interest in quitting smoking. If the patient is interested in quitting, the PN will offer and help to connect the smoker to existing cessation resources in the community and CHCs and provide follow-up contacts to monitor adherence to treatments. The PN will direct smokers to the 5-call proactive telephone smoking cessation counseling provided free by the MA Quitline. The PN will use a QuitWorks fax-referral system to make the Quitline referral; by doing so, the smoker is eligible for two weeks of free nicotine patch or gum as well. The PN will also explain that pharmacologic treatment doubles quit rates when added to behavioral counseling, describe the available FDA-approved smoking cessation medications (nicotine replacement products, bupropion, and varenicline), and refer to the PCP for a recommendation and prescription. The PN will monitor patient progress by contacting the patient weekly for up to six weeks, followed by monthly follow-up until the end of the study. If a patient declines smoking cessation assistance, the PN will continue to inquire every three months if the patient has changed his/her mind about cessation and/or LDCT screening. Navigators will record information on every patient they contact and note all the interventions that were attempted.

For the patient satisfaction surveys in Specific Aim 4, patients will be contacted by telephone and asked to participate if they received PN services as part of the lung screening PN program and have contact with the navigator. We will also randomly select patients from the delayed intervention/control group to complete a satisfaction survey.

For the PCP and nurse practitioner (NP) surveys in Specific Aim 5, PCPs and NPs will be provided a paper survey at regular practice meetings by the PI of this study and asked to complete the survey. Providers that do not attend the practice meeting will receive the request to fill out the survey via interoffice mail or email.

V. STUDY PROCEDURE

V.1. Overview

We propose to develop, implement, and rigorously evaluate a novel lung screening patient navigator program for patients that currently smoke in five community health centers affiliated with a primary care network of a large academic hospital.

Eligible patients will include those receiving care in community health centers who are 55-77 years old and currently smoking. The intervention trial will be randomized at the patient level. In the intervention group, patients will be contacted by a culturally competent PN who will help them stop smoking and obtain lung screening. The control patients will receive usual care. The primary outcome will assess the percentage of eligible patients in intervention and control groups who had at least one chest CT during the study period. Secondary outcomes will include as-treated primary outcomes among intervention patients contacted by the patient navigator, primary outcomes stratified by language spoken, race, age, and practice site, follow-up of abnormal results, percentage of patients with tobacco treatment, and comparison of lung screening to other practices in the primary care network.

V.2.   Time Line

As depicted in **Table 1**, the work planned for **Specific Aim 1** is occurring during Study Year 1. Development of the program, hiring and training navigators, as well as organizational aspects that are necessary to permit the timely implementation and evaluation of the intervention (**Specific Aim 2**) will occur over the course of Year 2 with completion in early Year 3. The remainder of Year 3 will be devoted to outcomes evaluation, **(Specific aim 3)** analysis, and dissemination.

Table 1. Project Timeline of Specific Aims and Tasks by 4 Month Periods									
Task	0-4	5-8	9-12	13-16	17-20	21-24	25-28	29-32	33-36
Specific Aim 1									
Develop smokers registry	██								
Software development for PN		██							
Develop curriculum and procedure manual for PN		██	░░						
Present the program at CHC PCP meetings		██	██						
Develop educational materials for patients		██	██						
Navigator training		██							
Specific Aim 2 and 3									
Randomization			██	░░					
Baseline evaluation				██					
Intervention				██	██	██	░░		
Outcome evaluation (at 1 year)							██	░░	
Analysis & manuscript writing								██	██
Dissemination								██	██
Note: Lighter shaded boxes denote option for additional time if needed.									

V.3.   Patient Navigation for Lung Screening at MGH Community Health Centers (Specific Aim 1)

In the first year of our study, we are developing a patient navigator program for lung screening for eligible patients – smokers aged 55-77 years receiving care at the CHCs affiliated with MGH. This includes:

1. We will take advantage of a registry of smokers aged 55-80 years being developed for the TopCare population management system in the MGH primary care network.
2. The PI is working with medical directors of the five CHCs to give an overview of new guidelines for LDCT lung screening along with details of the planned study at provider meetings.
3. We are interviewing candidates for PN position

4. We are developing a procedure manual for the program using previously developed manuals for existing PN programs at MGH as a template.
5. We are evaluating currently available shared decision lung screening tools to use for our study
6. We will train the PN on motivational interviewing, problem solving, IT system, electronic medical record documentation as well as smoking cessation and lung screening. We will create a procedure manual with phone scripts, talking points, time frame of the calls, templates to facilitate documentation in the medical record and communication with providers. Training and supervision during the study period will be provided by PI, PN manager and MGH Chelsea HC community heath director.

V.4.   Randomized Clinical Trial (Specific Aim 2)

To test our hypothesis we will randomize eligible patients receiving care at CHCs to one of two study groups:

Early intervention	Usual care/delayed intervention
400 patients will receive 1:1 PN to obtain lung screening and follow-up of abnormal results, as well as smoking cessation guidance	800 patients will receive usual care during the 1-year study period. After the study period they will be offered 1:1 PN to obtain lung screening and follow-up of abnormal results as well as smoking cessation guidance

Eligibility criteria:

1. Inclusion criteria: adult patients aged 55-77 years who are current cigarette smokers (according to an algorithm using EMR data), and receive care at one of the five MGH CHCs.
2. Exclusion criteria: 1) patients who have previously received a diagnosis of lung cancer per EMR, 2) have undergone a chest CT within 18 months before enrollment, 3) are subsequently identified as having died prior to the study intervention 4) deemed by their primary care provider as not eligible for lung screening

Patients will be identified using existing electronic systems developed by the MGH Primary Care Operations Improvement (PCOI) program (Protocol # 2004P002796).

Using a newly developed TopCare smoking and lung screening registry, we will identify smokers receiving care at MGH health centers who could be eligible for lung screening. We will e-mail primary care providers a list of their patients and ask them to notify us in a week if they do not want us to contact a patient and to provide a reason why they believe patient is not eligible for lung screening. The eligible patients will then be randomly allocated to the intervention or usual care groups. Patients randomly assigned to the intervention group will be eligible for PN, while patients randomly assigned to the control will receive usual care and be eligible for navigation after the one year period.

Patient navigator intervention:

PN program delivery: A letter about the program with lung screening educational materials used in usual clinical practice will be mailed to eligible patients. A week later, the PN will contact patients over the phone or in person during office visits. The letters will be sent in stages. First, PN will use TopCare IT system to identify patients who have appointment scheduled and send letters/contact them prior to their appointments. Patients who do not have appointments scheduled will be contacted in stages so that during the first 6 months of the study all eligible patients receive a letter and at least one phone call attempt from PN. During the initial contact, the PN will obtain detailed history to determine if patient is eligible for lung screening. The PN will educate patients about lung screening and explore any barriers to screening. If the patient is interested in screening, the PN will coordinate scheduling a shared decision-making appointment with a provider and, whenever feasible, attend the visit with the patient. The PN will further coordinate scheduling the CT scan if the provider and patient made that decision and navigate the patient to obtain the test. Further interventions may include:

reminding the patient about the test, helping with translation, insurance issues, transportation, and overcoming any other system barriers as needed. After screening, the PN will review the results. If the patient has an abnormal test result, the navigator will contact the patient's primary care physician and help the patient obtain required follow-up.

As a part of lung screening, the PN will assess the patient's interest in quitting smoking and provide motivational message about the importance of quitting despite having lung screening. If the patient is interested in quitting, the PN will offer and help to connect the smoker to existing cessation resources in the community and CHCs and provide follow-up contacts to monitor adherence to treatments. The PN will refer smokers to the 5-call proactive telephone smoking cessation counseling provided free by the MA Quitline. The PN will use a QuitWorks fax-referral system to make the Quitline referral; by doing so, the smoker is eligible for four weeks of free nicotine patch or gum as well. The PN will also offer refer to in-person counseling from CHC tobacco coach. Additionally, the PN will explain that pharmacologic treatment doubles quit rates when added to behavioral counseling, describe the available FDA-approved smoking cessation medications, and refer to the PCP for a recommendation and prescription of bupropion or varenicline, which are available only by prescription. The PN will monitor patient progress by trying to contact the patient up to 3 times over 1-2 months period to make sure that patient received smoking cessation intervention referred to. Navigator will record information on every patient they contact and note all the interventions that were done.

V.5. Prospective Data Collection for Disparities in LDCT and Smoking Cessation (Specific Aim 3)

To determine whether the patient navigator program maintained equity in obtaining lung screening among smokers from CHCs compared to smokers from other MGH primary care practices, we will examine lung screening rates in the two study populations in the year prior to the intervention and after the 1-year intervention period. Eligibility criteria are the same as in Specific Aim 2, except the analysis will include patients in all MGH affiliated primary care practices stratified by CHC or other.

Lung screening rates prior to and after the 1-year intervention period will be compared among eligible patients receiving care at one of the five MGH CHCs (all patients and subgroup of those who received the early intervention) and eligible patients from all other MGH practices.

Patients will be identified using existing electronic systems developed by the MGH PCOI program (Protocol # 2004P002796).).

V.6. Patient Satisfaction Surveys (Specific Aim 4)

We plan to collect quantitative data about patient satisfaction with the navigators in Lung screening patient navigation (PN) program. We will ask patients who have been randomized to PN early intervention arm to complete two validated surveys: "Satisfaction with Interpersonal Relationships with Navigator (PSN-I)" and "Satisfaction with Logistical Aspects of Navigation (PSN-L)". We will also ask both the PN early intervention group and the delayed intervention group to complete the Short-form Patient Satisfaction Questionnaire (PSQ-18). These surveys will provide information about patient satisfaction with the PN program and information about the impact of the PN program on overall patient satisfaction with medical care.

Patients will be contacted by telephone and asked to participate if they received PN services as part of the Lung screening PN program and had contact with navigator. Those interested in participation may then complete the surveys over the telephone or they may elect to complete the surveys in person and will be met by an interviewer at their next MGH clinic appointment. Patient interviews will last approximately 20 minutes in duration (see attached surveys and interview guide). Bilingual research assistants or trained interpreters will be available to conduct surveys if patients are not native English speakers. Exclusion and inclusion criteria are the same as Specific Aim 2.

V.7.   Provider Surveys (Specific Aim 5)

Following the completion of the randomized trial of the lung cancer screening PN program in current smokers receiving primary care at MGH CHCs, we plan to survey primary care providers to assess their opinions and experience with the program with a short 8 question survey. The study PI will visit the 5 CHCs at regularly scheduled practice meetings to present the overall results of the randomized trial, and will ask PCPs and NPs from these practices to complete a paper version of the survey at the meeting. For providers who do not attend the meeting, we will send them the survey via interoffice mail or email. The survey will not collect any personal or demographic data. All providers from the participating practices will be eligible to receive the survey.

VI.   BIOSTATISTICAL ANALYSIS

VI.1   Primary outcomes (intention-to-treat)

Percentage of patients assigned to the intervention and control groups who had at least one chest CT (according to billing and EMR data) during the 1-year study period.

VI.2   Secondary outcomes

1. Percentage of patients who had at least one chest CT (according to billing and EMR data) during the 1-year study period, comparing patients contacted by patient navigator in the intervention group ("as treated" analysis) vs. all patients in control group.
2. Percentage of patients in intervention vs. control groups who had at least one lung CT screening stratified by language spoken, race, age (<> 65 years) and practice site. (subgroup analysis)
3. Of patients whose initial chest CT generated a radiologist's recommendation for early interval follow-up, the percentage who received the recommended follow-up of in timely manner. The timeliness of care is defined by radiologist's recommendation plus additional 30 days. For recommended biopsy/PET scan we chose 60 days limit. All radiologists at MGH use Lung-RADS system to recommend the follow up post LDCT. These standardized recommendations include 12, 6 or 3 months follow up or for suspicious malignancy PET CT vs biopsy. There is some variability in reading diagnostic chest CT; however recommendations are similar to Lung-RADS. At the end of one-year trial a blinded research assistant will review the electronic medical records of patients who had a chest CT during study period. The dates of imaging will be confirmed by billing data.
4. Mean time to follow-up of abnormal results, comparing intervention and control groups.
5. Tobacco treatment use: Percentage of patients, comparing intervention and control groups, who during the 1-year study period had any of the following:
   o   referral to MA Quitline as determined by patients' QuitWorks data or referral scanned in EHR
   o   smoking cessation medication prescribed in EHR (nicotine patch, gum. lozenge, inhaler, nasal spray or bupropion, or varenicline) during the study period
   o   referral to in-person counseling from CHC-based tobacco coach –documented in EHR
6. Percentage of patients, comparing intervention and control groups, who have a status of former or nonsmoker entered in coded field of EHR at the visit closest to the date of 1 year follow-up.
7. Percentage of patients in intervention group who are reached by PN and percentage of patients reached who had lung screening (process measures)

AIM 3
Outcome measure
Percentage of current smokers aged 55-77 years at baseline who have a chest CT in the subsequent 1 year, comparing patients receiving care at CHCs with patients from all other practices within the MGH primary care network.

VI.3. Analytic Methods

AIM 2:
We will examine differences in lung screening rates using chi-square tests.
The comparisons include (1) between intervention and control groups (intention-to-treat analysis), and (2) between patients contacted and not contacted by patient navigators ("as-treated" analysis).
An exploratory subgroup analysis will compare lung screening rates between intervention and control groups stratified by language spoken, race, age (<> 65 years), practice site and other factors.
Furthermore, we will use logistic regression models to examine predictors of lung screening, including patient, provider, and practice characteristics.
In addition to comparing the percentage that completed recommended test in a timely manner between intervention and control group using a chi-square test, we will use survival analysis techniques to compare time to completion between intervention and control groups.
We will also use chi-square tests to compare the percentage with referral to MA Quitline, prescription to smoking cessation medications, referral to in person counseling from CHC tobacco coach, and documented smoking status in EHR between intervention and control groups.
For the intervention group, we will document process measures (percentage reached by PN and percentage agreed to have lung screening test within) and present with 95%CI's.

AIM3:
We will use a chi-square test to compare lung screening rates between patients receiving care at CHCs to patients from other practices within the MGH primary care network during the one-year study period.

Aim4:
We will use chi-square tests and/or t-tests as appropriate to compare patient satisfaction between navigated and non-navigated patients.

VI.4. Sample Size Calculations

We hypothesize that the navigator program will increase lung screening in the intervention group by at least 5%. With a total sample size of 1276 smokers, 400 randomized to the intervention group, and an alpha level of 0.05, we will have 88% power to detect a 5% difference. From our prior experience, a full time navigator with the assistance of two part-time interpreters/navigators can reach about 400 patients over nine months. Since our intervention includes follow-up of abnormal results, our study will last 1-year.

VII. RISKS AND DISCOMFORTS

We see no significant risks to patients as a result of this study. Patients the intervention group will be contacted by a culturally competent PN who will assess their interest in lung screening. For some individuals this information may cause distress if it is something they are not interested in doing or if they do not think it accurately reflects their particular situation. This information may also not be up to date for all patients. If an individual believes this is the case, he/she will be provided information about whom to contact to update their records. A standard system is in place as part of usual care to input this information into the patient's electronic medical record to communicate this information. All contact with patients, including those in the control group, will be based on current MGH Primary Care guidelines for usual care.

Specific Aim 4: There are no foreseeable risks from participating in this quantitative interview study except the time commitment required and the possibility of psychological discomfort in discussing the subject of cancer prevention. Demographic information will be obtained from electronic medical record. All data will be stored on password-protected computers. Personal health information will be de-identified during data collection. All identifying patient information will be deleted prior to analysis and data will only be presented in aggregate.

Specific Aim 5: There are no foreseeable risks from completing this survey. No personal or demographic information will be collected. Providers may decline to complete the survey if they wish.

VIII. POTENTIAL BENEFITS

Patients may benefit from the intervention if it results in smoking cessation and lung screening. Such screening may decrease the individual's risk of being diagnosed with cancer, or if diagnosed it may be at a stage where treatment is more effective.

If the intervention is effective in improving care, resources may be expanded to reach more vulnerable patients across the primary care network in a timelier manner.

Specific Aim 4: There is no direct benefit to subjects from participating in this additional portion of the study. The study is not specifically designed to facilitate patients having cancer screening; rather, it simply seeks to explore patients' experience with current PN programs. The knowledge gained from this study of patient's experience and satisfaction with PN programs will guide quality improvements of patient care at MGH by modifying current PN programs depending on patient feedback.

IX. MONITORING AND QUALITY ASSURANCE

All study personnel are experienced clinical investigators and have completed required IRB-related programs. Study investigators and research personnel have extensively used data sources as part of clinical quality improvement and research activities that will be employed in this study. Regular meetings involving study investigators and staff will be held to ensure the validity, integrity, and timeliness of the data, and adherence to the IRB-approved protocol and Partners Human Research Committee policies.

IX.1. Data Safety and Monitoring

Because potential risks to patients are minimal, patients will receive standard care, and the period of intervention short, we do not plan to employ a Data Safety Monitoring Board and have chosen not to employ formal interim analyses or guidelines for early termination of this short trial. In the event that adverse events are found to occur more often in either study group, we will alert the Partners HealthCare System IRB as soon as we are aware and take further action as needed.

The PI will report adverse events or other unanticipated problems to the PHRC as described in the PHRC policy on Adverse Event Reporting and Unanticipated Problems Involving Risks to Subjects or Others.

IX.2. Privacy and Confidentiality

All data will be stored on password-protected computers, and personal health information will be de-identified during data collection and only decoded as necessary to link back to patient outcome information. Only IRB approved study personnel will perform and have access to confidential patient data. All data sources used as part of this study are maintained by MGH and Partners and meet current HIPAA requirements. All MGH patients are informed that patient data may be used for clinical research. All identifying patient information will be deleted prior to analysis and data will only be presented in aggregate. Any printed forms with patient data will be stored in a locked cabinet or shredded.

X.   REFERENCES

1. National Lung Screening Trial Research T, Aberle DR, Adams AM, Berg CD, Black WC, Clapp JD, Fagerstrom RM, Gareen IF, Gatsonis C, Marcus PM, and Sicks JD. Reduced lung-cancer mortality with low-dose computed tomographic screening. *N Engl J Med.* 2011;365:395-409.
2. National Lung Screening Trial Research T, Church TR, Black WC, Aberle DR, Berg CD, Clingan KL, Duan F, Fagerstrom RM, Gareen IF, Gierada DS, Jones GC, Mahon I, Marcus PM, Sicks JD, Jain A, and Baum S. Results of initial low-dose computed tomographic screening for lung cancer. *N Engl J Med.* 2013;368:1980-1991.
3. Bach PB, Mirkin JN, Oliver TK, Azzoli CG, Berry DA, Brawley OW, Byers T, Colditz GA, Gould MK, Jett JR, Sabichi AL, Smith-Bindman R, Wood DE, Qaseem A, and Detterbeck FC. Benefits and harms of CT screening for lung cancer: a systematic review. *JAMA.* 2012;307:2418-2429.
4. Humphrey LL, Deffebach M, Pappas M, Baumann C, Artis K, Mitchell JP, Zakher B, Fu R, and Slatore CG. Screening for lung cancer with low-dose computed tomography: a systematic review to update the u.s. Preventive services task force recommendation. *Ann Intern Med.* 2013;159:411-420.
5. Croswell JM, Baker SG, Marcus PM, Clapp JD, and Kramer BS. Cumulative incidence of false-positive test results in lung cancer screening: a randomized trial. *Ann Intern Med.* 2010;152:505-512, W176-580.
6. Decision memo for screening for lung cancer with low dose computed tomography (LDCT) (CAG-00439N). https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274. Accessed September 27, 2015.
7. Freund KM. Patient navigation: the promise to reduce health disparities. *J Gen Intern Med.* 2011;26:110-112.
8. Paskett ED, Harrop JP, and Wells KJ. Patient navigation: an update on the state of the science. *CA Cancer J Clin.* 2011;61:237-249.
9. Wells KJ, Battaglia TA, Dudley DJ, Garcia R, Greene A, Calhoun E, Mandelblatt JS, Paskett ED, Raich PC, and Patient Navigation Research P. Patient navigation: state of the art or is it science? *Cancer.* 2008;113:1999-2010.
10. Freeman HP, Muth BJ, and Kerner JF. Expanding access to cancer screening and clinical follow-up among the medically underserved. *Cancer Pract.* 1995;3:19-30.
11. Braun KL, Kagawa-Singer M, Holden AE, Burhansstipanov L, Tran JH, Seals BF, Corbie-Smith G, Tsark JU, Harjo L, Foo MA, and Ramirez AG. Cancer patient navigator tasks across the cancer care continuum. *J Health Care Poor Underserved.* 2012;23:398-413.
12. Jandorf L, Gutierrez Y, Lopez J, Christie J, and Itzkowitz SH. Use of a patient navigator to increase colorectal cancer screening in an urban neighborhood health clinic. *J Urban Health.* 2005;82:216-224.
13. Lasser KE, Murillo J, Lisboa S, Casimir AN, Valley-Shah L, Emmons KM, Fletcher RH, and Ayanian JZ. Colorectal cancer screening among ethnically diverse, low-income patients: a randomized controlled trial. *Arch Intern Med.* 2011;171:906-912.
14. Naylor K, Ward J, and Polite BN. Interventions to improve care related to colorectal cancer among racial and ethnic minorities: a systematic review. *J Gen Intern Med.* 2012;27:1033-1046.
15. Battaglia TA, Bak SM, Heeren T, Chen CA, Kalish R, Tringale S, Taylor JO, Lottero B, Egan AP, Thakrar N, and Freund KM. Boston Patient Navigation Research Program: the impact of navigation on time to diagnostic resolution after abnormal cancer screening. *Cancer Epidemiol Biomarkers Prev.* 2012;21:1645-1654.
16. Hoffman HJ, LaVerda NL, Young HA, Levine PH, Alexander LM, Brem R, Caicedo L, Eng-Wong J, Frederick W, Funderburk W, Huerta E, Swain S, and Patierno SR. Patient navigation significantly reduces delays in breast cancer diagnosis in the District of Columbia. *Cancer Epidemiol Biomarkers Prev.* 2012;21:1655-1663.
17. Markossian TW, Darnell JS, and Calhoun EA. Follow-up and timeliness after an abnormal cancer screening among underserved, urban women in a patient navigation program. *Cancer Epidemiol Biomarkers Prev.* 2012;21:1691-1700.
18. Raich PC, Whitley EM, Thorland W, Valverde P, Fairclough D, and Denver Patient Navigation Research P. Patient navigation improves cancer diagnostic resolution: an individually randomized clinical trial in an underserved population. *Cancer Epidemiol Biomarkers Prev.* 2012;21:1629-1638.

19. Wells KJ, Lee JH, Calcano ER, Meade CD, Rivera M, Fulp WJ, and Roetzheim RG. A cluster randomized trial evaluating the efficacy of patient navigation in improving quality of diagnostic care for patients with breast or colorectal cancer abnormalities. *Cancer Epidemiol Biomarkers Prev.* 2012;21:1664-1672.
20. Percac-Lima S, Ashburner JM, Bond B, Oo SA, and Atlas SJ. Decreasing Disparities in Breast Cancer Screening in Refugee Women Using Culturally Tailored Patient Navigation. *J Gen Intern Med.* 2013.