A Pragmatic Randomized-Controlled Trial of a Digital Outreach Intervention for Lung Cancer Screening: mPATH-Lung (mobile Patient Technology for Health-Lung)
Wake Forest Baptist Comprehensive Cancer Center (WFBCCC)
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WFBCCC # TBD

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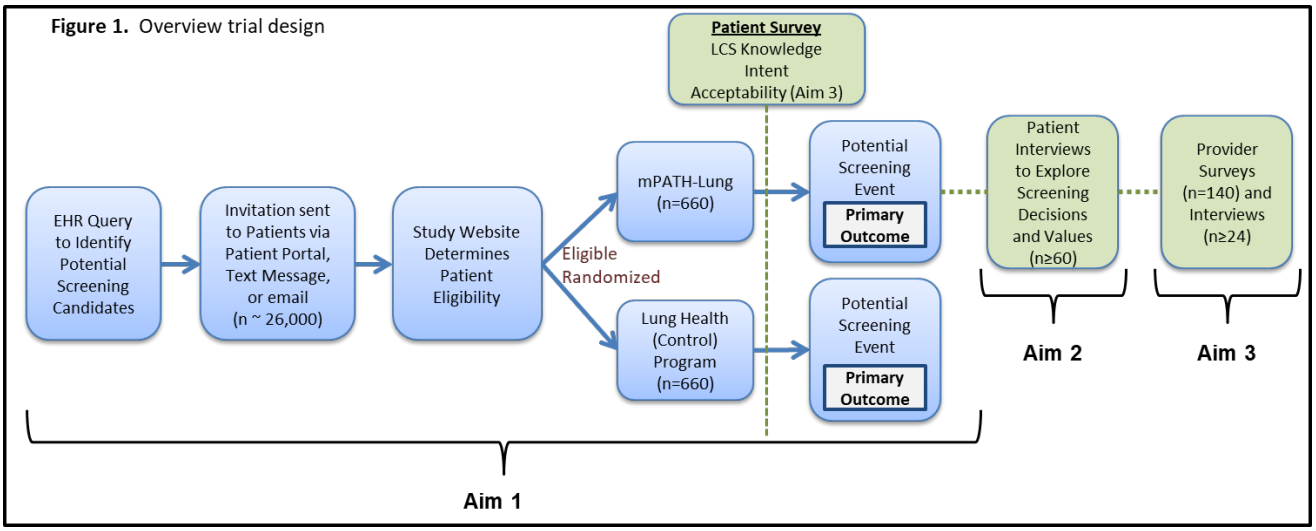
ABSTRACT AND SCHEMA

mPATH-Lung (mobile Patient Technology for Health – Lung) is a digital outreach strategy for lung cancer screening (LCS). mPATH-Lung (a) queries the electronic health record (EHR) to identify potential screening candidates, (b) sends those individuals electronic invitations to visit a web-based LCS decision aid that confirms eligibility and provides personalized information, and (c) lets patients electronically request an LCS clinic appointment.

Our study design is depicted below in **Figure 1**. We will examine the effect of mPATH-Lung on receipt of Lung Cancer Screening (LCS) (**Aim 1**) in a patient-level pragmatic-design randomized controlled trial of 1320 primary care patients conducted in two large health networks with a catchment area extending to five states. We will send potentially eligible patients electronic invitations to visit our study website, which will determine eligibility and randomly assign patients to interact with either mPATH-Lung or an educational program about exercise for lung health. Patient knowledge, screening intent, and screening outcomes will be assessed by surveys and review of the Electronic Health Record EHR. Additionally, we will use mixed methods to elucidate the drivers of patients' LCS decisions (**Aim 2**), and assess implementation outcomes that will inform scalability and dissemination (**Aim 3**).



1.0 Introduction and Background

Lung cancer is the leading cause of cancer death in the United States.[1] In 2019, over 140,000 Americans will die of lung cancer, a number that is greater than those that will die from breast, prostate, and colorectal cancer combined.[1,2] Over 80% of lung cancers are diagnosed at advanced stages when cure is not possible and 5-year survival is only 5-30%. However, if diagnosed early at a localized stage, 5-year survival is 56%.[2]

In 2011, the ground-breaking National Lung Screening Trial (NLST) demonstrated that annual screening with low-dose computed tomography (CT) decreases lung cancer mortality by 16-20%.[3,4] Currently, several organizations (e.g., the US Preventive Services Task Force, the American Cancer Society, and the American Thoracic Society) endorse LCS for high-risk current and former smokers,[5–7] and Medicare has approved LCS reimbursement for high-risk patients aged 55 to 77 years.[8] Commercial insurers also cover LCS. Nonetheless, in 2015, fewer than 4% of eligible patients were screened.[9]

While LCS lowers lung cancer mortality, it also carries some risk. Thirty-nine percent of screened individuals in the NLST had at least one false positive after three screening rounds, leading to costly and sometimes invasive follow-up procedures that did not find cancer.[3,10] Screening may also detect indolent cancer that never would have affected the patient during his or her lifetime – leading to overtreatment and possible physical, psychological, and financial harms.[11–13] Thus, current guidelines recommend and Medicare requires that providers engage in shared decision making with their patients before initiating screening.[5–8]

Helping patients make an informed LCS decision is a complex task because the harms and benefits vary according to individuals' risk factors. As an example, in the NLST, the number needed to screen to save one life ranged from 161 to 5276 depending on a patient's risk of developing lung cancer.[14] Similarly, the number of false positives per life saved ranged from 65 to 1648.[14] This wide variation highlights the critical importance of providing patients with personalized information so they can make an informed decision.

Shared decision making also requires helping patients consider their own unique values. Patients consider multiple factors when making decisions about cancer screening[15–17] and weigh them differently (often unconsciously). Helping patients clarify which factors are most important to them, a process known as values clarification, is a critical aspect of a high-quality shared decision making process.[18–20] However, we have limited understanding of what factors drive patients' LCS decisions. Qualitative studies found that patients consider several factors in such decisions, including the mortality benefit, chance of false positives, emotional (anxiety) factors, and practical barriers (costs, transportation); but a weakness of current research is that how they weigh these factors to reach a decision is unclear.[21–27] Furthermore, to our knowledge, no studies have examined interventions to help patients clarify their values and preferences for LCS in routine care.

Multilevel barriers contribute to the low screening rates observed. Unfortunately, our current medical care system relies on time-pressured primary care providers to hold these complex discussions with patients, and primary care providers report lack of time as a leading barrier to providing guideline-recommended preventive care.[28–34] In addition, many providers are unfamiliar with LCS guidelines.[28,29,35–37] Miller (PI) and Bellinger (Co-I) were the first to document that only half of primary care providers could correctly identify 3 of 6 basic eligibility criteria for LCS.[38] Given these obstacles, providers rarely discuss or order LCS.[34,36,39,40] Members of our team searched transcripts from over 5000 primary care visits and found that LCS was discussed with only 14 patients and explanation of potential harms of screening was virtually nonexistent.[41] Similarly, many patients are unaware of the availability of LCS or its value.[21,35]

Decision aids are a partial solution. Currently available decision aids can increase patients' knowledge of LCS,[16,42–44] deliver some personalized information,[16,45] and help patients make a screening decision.[16,43] They can also mitigate providers' knowledge deficits by offering an

evidence-based, standardized format for providing patients with information about LCS. However, none provide patients with personalized information about the likelihood of the harms of screening, nor do they explicitly incorporate values into the decision making process.[45] Additionally, while physicians have endorsed LCS decision aids as helpful,[28] their use still requires time and they fail to address system barriers such as coordinating screening visits and insurance pre-approval. In two pilot studies conducted by members of our team, less than half of patients who wanted screening after watching an LCS decision aid received it.[16,46]

To address these multilevel barriers to LCS and the need for personalized, shared decision making, our team has developed mPATH-Lung (mobile Patient Technology for Health – Lung), a user-friendly web-based application that can be systematically deployed to prepare patients and providers for meaningful shared decision making visits and help coordinate screening. mPATH-Lung addresses patient barriers by informing patients of LCS, providing them with personalized risk-benefit information, and helping them make decisions consistent with their values. mPATH-Lung addresses provider knowledge and time barriers by determining patient eligibility for LCS, assisting with routine counseling, and streamlining shared decision making visits. mPATH-Lung addresses system barriers by leveraging technology to reach patients where they are, facilitating LCS visit scheduling and insurance preapprovals, and automatically routing program usage information to primary care providers.

We designed mPATH-Lung with a screen adaptable design, allowing it to be used on smartphones or any other device. Over 75% of Americans own a smartphone.[47] While a digital divide exists for home broadband use, there is no racial/ethnic digital divide for smartphone ownership.[47] Smartphone ownership exceeds 67% even for those with annual household incomes less than $30,000 or only a high school education,[47] and ownership continues to rise.

This study will examine mPATH-Lung's effectiveness, elucidate the factors that drive patients' screening decisions, and explore the potential for future dissemination and implementation using widely-accepted implementation frameworks.

2.0 Objectives

2.1 Primary Objective

- Determine the effectiveness of mPATH-Lung on receipt of LCS in a randomized pragmatic clinical trial of 1320 patients recruited from two large health networks, Wake Forest Baptist Health and the University of North Carolina at Chapel Hill.

2.2 Secondary Objectives

- Elucidate the drivers of patients' decisions to receive or forgo LCS through a values clarification exercise embedded within mPATH-Lung and supplemental semi-structured interviews of at least 50 patients.

- Assess several critical implementation outcomes (reach, acceptability, and appropriateness) to inform the sustainability and scalability of mPATH-Lung across diverse primary care settings

3.0 Study Population

3.1 Inclusion Criteria

Eligible patients will:

- Meet the Medicare criteria for LCS, as updated in February 2022:
  - Age 50 – 77 years
  - Smoked at least 20 pack years
  - Current smoker or quit smoking within the past 15 years
- Be scheduled to see a primary care provider within the health network in the next 3-4 weeks
- Have a patient portal account or cellphone number listed in the EHR

3.2 Exclusion Criteria

The following patients will be excluded:

- Patients flagged as needing a language interpreter in the EHR (electronic messages and intervention is delivered in English only)
- Those for whom LCS would be inappropriate:
  - Prior history of lung cancer
  - Chest CT within the last 12 months
  - Those with medical conditions predicting shorter life expectancy
- Patients whose home address is not within the state of North Carolina. (Due to telehealth guidelines)

3.3 Inclusion of Women and minorities

Women and men of all races and ethnicity who meet the above-described eligibility criteria are eligible for this trial.

4.0 Methods

4.1 Study Sites

The study will be conducted in two large academic-affiliated health networks (Wake Forest Baptist Health and UNC) that have over 200 community-based primary care clinics with approximately 900 PCPs and a catchment area covering all of North Carolina and extending to four neighboring states, including portions of rural Appalachia. In 2018 both networks saw 165,601 “ever smokers” who were potentially eligible for LCS based on age. Both health networks have the same EHR (Epic™, Verona, WI) that is shared by all of their clinics.

LCS programs and usual care. Both networks have well-established LCS programs. Patients, who may self-refer to the LCS program, meet with a provider who confirms screening eligibility, conducts a shared decision making visit in accordance with CMS guidelines,[8] and orders the screening CT. Afterwards, the LCS clinic communicates results to the patient and arranges any needed follow-up testing. Primary care providers may also order screening CTs directly, in which case they must conduct the shared decision making visit, communicate results, and order any needed follow-up testing. Both networks broadly advertise their LCS programs to patients via web campaigns, posters, and mailings. Despite these efforts, only 2% of those potentially eligible in 2018 (3,215 of 165,601) were screened.

4.2 Registration Procedures

Patients will be participating in a pragmatic trial in which patient data collection will occur by retrospective electronic chart review. All patients will receive current guideline-recommended care, and we will request a waiver of patient Informed Consent. Therefore, it is impractical to register patients with the Cancer Center, and any such registration would jeopardize patient confidentiality.

Following primary data collection, a subset of patients and clinic providers will participate in interviews and/or surveys related to the study's secondary objectives. No sensitive information will be collected from these participants. Therefore, we are requesting a waiver of signed consent. We will give these participants a study information sheet explaining the purpose of the study, the nature of the data to be collected, and the voluntary nature of their participation.

4.3 Participant Recruitment

We will identify eligible participants for this pragmatic trial in two phases.

Phase One (Sending electronic invitations): Each week we will query the EHR to identify potentially eligible participants based on the inclusion and exclusion criteria. We will oversample for non-white patients, and we will send identified patients an electronic invitation with an embedded hyperlink to our study website. The invitation text can be found in Appendix L. The hyperlink contains an anonymous study identifier unique to each patient, allowing us to track who visits the study website, an approach we successfully used in our pilot study.[46]

Table 1. Accuracy of Smoking History in the EHR Compared with Patient Self-Report

Self-reported smoking history	Accurately recorded
Ever smoker,	100% (336)
Years since quitting	44% (149)
Pack-years smoked (+/- 5	20% (35)

As shown in Table 1, our preliminary data indicate the EHR accurately captures whether patients ever smoked (current or former smokers), but not years since quitting or pack-years. Therefore, our query will include all ever smokers, and the study webpage will gather additional detailed smoking history from patients to determine eligibility. Overall, 90% of our target sample has a patient portal account, mobile phone, or email address on file. Patients with an active portal account (defined as ≥1 logins over the past 90 days) will receive a message via MyChart. Those without a patient portal account will be sent a text message. Text message recipients will receive up to one additional reminder text message 3-7 days after the initial communication.

The study team will ensure each institution's patient consent forms cover the use of text messaging for this pragmatic trail before the invitations are sent.

Phase Two (Confirming eligibility via study website): When patients click on the hyperlink, it will take them to the study homepage. The site employs a user-friendly interface we have previously validated in low- and high-literacy patients.[49] The homepage will inform patients that the website was developed by researchers, will ask them a few questions to determine if they meet guideline criteria for lung cancer screening, and will then show them a brief video. The homepage will also specify that by proceeding, they understand their deidentified data may be used. This study qualifies for exemption under 45 CFR 46.101.

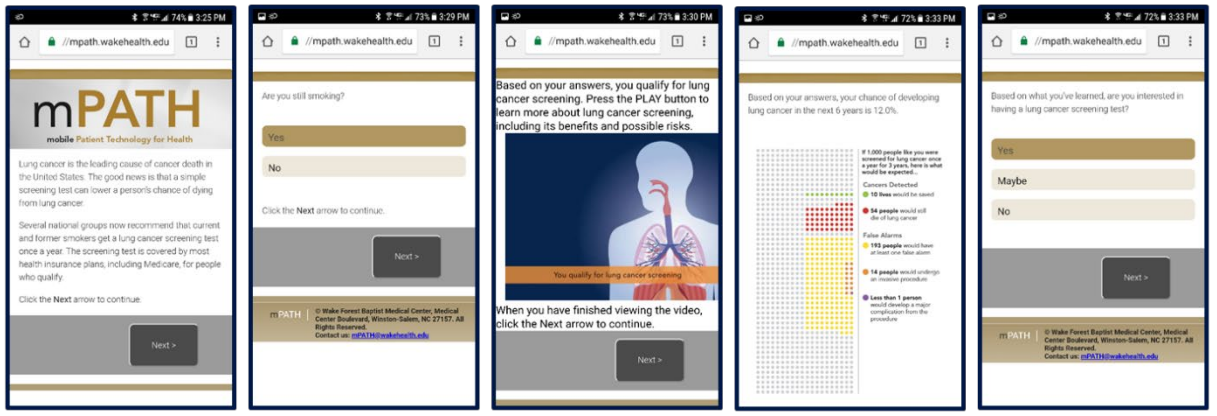
Potential participants will complete a brief self-survey on the website (Appendix A) to gather additional smoking history and determine if they meet eligibility criteria for LCS (as described above in Phase One). If patients are eligible for LCS, the study program will randomly assign them, stratified by health system network, to either mPATH-Lung or a control program about exercise for lung health using stored random

permutated blocks. Patients who are ineligible also will be shown the control program, but they will be excluded from the study.

4.4 mPATH-Lung Intervention

Planned Updates to mPATH-Lung: We have extensively tested the beta version of mPATH-Lung (Figure 2) which determines if patients are eligible for LCS via a self-survey, shows eligible patients a brief video decision aid, and then invites them to estimate their personal risks and benefits of screening by completing 8 survey items needed to calculate their predicted risk of developing lung cancer based on the validated Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial Model 2012.[14,46,50] Patients' risks of developing lung cancer are used to estimate their anticipated benefits (lives saved) and harms (false positives, invasive procedures, and complications) of screening, based on a model our team developed.[45,46,51] This benefit-harm information is displayed to patients as an infographic, the format that maximizes engagement and comprehension, particularly for patients with low literacy or numeracy skills.[52,53] Patients who decline to estimate their personal risks are shown an infographic summarizing the benefits and harms for the average risk individual in the NLST cohort. The beta version concludes by asking patients if they want to receive screening and then providing them with the phone number for the LCS clinic.

Figure 2. Overview of the mPATH-Lung Web Application



Screen adapatable design runs on smartphones, tablets, or PCs | Determines LCS eligibility | Shows LCS Decision Aid | Calculates Personalized Risks and Benefits of LCS | Assists with LCS Appointments

In preparation for this proposed trial, we will update the beta version with four new features outlined below.

Video Decision Aid ***(Appendix B)***: The beta version of mPATH-Lung includes a short animated proof of concept video that reviews the general risks and benefits of LCS. We will replace this with an extensively tested, professionally developed LCS video decision aid that includes a strong message about the importance of tobacco cessation.[42,44,54] The video will explicitly address the risks and benefits outlined in Table 2, including screening-related anxiety and overscreening.

Values Clarification Exercise ***(Appendix C)***: Helping patients clarify how they balance the potential benefits and harms of screening is a critical element of shared decision making. An explicit values clarification exercise can help patients make a screening decision consistent with their values.[18] Patients will complete the exercise immediately after seeing their personalized risk-benefit infographic (see Figure 2, fourth panel from left). The exercise will be adapted from previously tested values clarification instruments, including some developed by our team members.[15,55] First,

patients will complete a rating exercise, in which they will rate the importance of the risks and benefits, or "attributes," of the screening decision (e.g., 193 out of 1000 chance of a false positive, or 10 lives saved out of 1000) individually on a 5-point Likert scale. Attributes rated will be the same as the risks and benefits of screening covered in the video decision aid (Table 2). Afterwards, patients will complete a ranking exercise, in which they will indicate their top two attributes in order of personal importance. Finally, patients will indicate their screening preference. To maximize readability, clarity, and comprehension, we will cognitively test the values clarification exercise using "think aloud" exercises with 10-15 patients who are eligible for LCS. In this pre-test, patients will complete the values clarification exercise and a cognitive interview to help us evaluate each item's performance (e.g., whether the content is understood in the intended manner, ease of completion) and clarity of the instructions. We will use results to iteratively improve materials between pre-testing sessions (e.g., revise wording for clarity). Patients who participate in this pre-testing phase will receive $50 for their time and will be ineligible for the larger study.

Electronic Summaries: On completion of mPATH-Lung, participants will be given the option to download a program summary including their personalized risk-benefit infographic, values clarification results, and screening decision.

Table 2. Risks/benefits (attributes) of screening addressed in mPATH-Lung

Averting death from lung cancer
Worry/anxiety over an abnormal scan
Experiencing a false alarm
Undergoing an invasive procedure
Having a serious complication from an unnecessary procedure
Finding a slow growing or harmless cancer and needlessly treating it
Radiation exposure

Electronic Requests for an LCS Clinic Visit: We will update mPATH-Lung so that patients can request an LCS clinic appointment directly from the program, mitigating the scheduling barrier. mPATH-Lung will present a webform to patients who indicate a desire to be screened. A study team member will send this information to the lung cancer screening clinic staff via the EHR so that they may contact the patient to schedule the appointment. The information in the webform will be accompanied by a statement that the patient used mPATH-Lung, was confirmed eligible for LCS, and is requesting a screening clinic appointment. Patients' answers to each eligibility item will be included to aid in insurance precertification so that the shared decision making visit can end with same-day screening if indicated. For patients who request a screening clinic appointment, the study team member will also upload a copy of the patient's program summary to the EHR. While patients will still engage in the Medicare-mandated shared decision making visit in the LCS clinic or primary care office, the easily retrieved mPATH-generated program summary in the EHR will allow the visit to proceed efficiently.

Patients who indicate an uncertainty about screening will be encouraged to discuss their concerns with their primary care provider at their upcoming appointment. As noted in our study inclusion criteria, all invited patients will have a primary care appointment in the next 3-4 weeks.

White Box Testing: We will use white box testing methods[56] to ensure the revised version of mPATH-Lung functions as planned. White box testing involves entering sequences of data purposively designed to test all failsafes and features of the program, including the accuracy of data collection.

Usability Testing (**Appendix M**)*:* Prior to commencing the pragmatic trial, we will conduct usability testing to ensure the mPATH-Lung program is appropriately designed for the target population. A study team member will meet individually with participants to observe them using the mPATH-Lung program following a Concurrent Think Aloud method.

Final mPATH-Lung Structure: Patients will proceed through mPATH-Lung as outlined below.

1. Study website determines LCS eligibility
2. If eligible, LCS decision aid video displayed
3. Personalized risks-benefits of screening calculated and displayed as an infographic.
4. Valued clarification exercise conducted
5. Patient asked if they would like to receive LCS
    a. If patient answers “yes” or “maybe”: webform presented for patient to request a LCS visit of desired
    b. If patient answers “no”: patient encouraged to discuss LCS with primary care provider
6. Patient given option to download an electronic summary

4.5 Control (usual care)

Patients randomized to the control arm will be told they meet guideline criteria for lung cancer screening, and they will be told to talk to their doctor “to see if screening is right for you.” However, control arm patients will not be shown the LCS decision aid, offered the opportunity to estimate their predicted benefits and harms of screening, or given the option of requesting a LCS screening visit via the program. Instead, control arm patients will see an animated video about exercise for lung health based on recommendations from the European Lung Foundation.[57] **(Appendix D)**

All patients will be exposed to each network’s standard LCS outreach efforts, and they will be scheduled to see a primary care provider within the next 3-4 weeks as part of the eligibility criteria – another opportunity for LCS to be addressed. As noted previously, patients in both health systems may self-refer for LCS as part of usual care.

4.6 Piloting Study Procedures

Prior to beginning enrollment of the study cohort, we will pilot these procedures on a subset of patients meeting our inclusion criteria. The purpose of this will be to ensure the automated processes function appropriately, and that accrual rates align with what is anticipated. We will create a pilot study database to validate our data queries and refine our data collection processes. However, data from participants in the pilot phase will not be included in the study analyses.

5.0 Outcome Measures

5.1 Primary Outcome

The primary outcome will be EHR-verified completion of a screening CT within 16 weeks of enrollment. While not all patients who are eligible for LCS will choose to receive it, we expect to see a significant difference in receipt of screening between arms if mPATH-Lung is effective. This will be defined as ANY chest CT within 16 weeks (and we will code to know whether it was a LDCT or some other diagnostic chest CT).

5.2 Secondary Outcomes

5.2.1 LCS screening decisions: LCS screening decisions will be captured by the mPATH-Lung program in the mPATH-Lung group only. (Time frame = post-intervention)
5.2.2 LCS clinic visits scheduled: The proportion of patients in each arm who have scheduled a LCS clinic visit will be captured by querying the EHR at each site.
5.2.3 LCS clinic visits completed: The proportion of patients in each arm who have completed a LCS clinic visit will be captured by querying the EHR at each site.
5.2.4 LCS scans ordered: The proportion of patients in each arm for whom a LCS scan was ordered will be captured by querying the EHR at each site.
5.2.5 LCS Clinic referral requested through mPATH
5.2.6 Lung RADS Results: The results of all chest CTs will be captured by querying the EHR at each site.
5.2.7 LCS false positives: A false positive scan will be defined as a Lung-RADS 3 or 4 result with a negative completed work-up for lung cancer or no diagnosis of lung cancer within 12 months of the scan.
5.2.8 Invasive procedures following LCS scan: We will query the EHR at each site to determine the number and proportion of patients in each arm who undergo an invasive procedure to investigate an abnormal LCS scan.
5.2.9 Complications following LCS: We will query the EHR at each site and conduct a blinded chart review to determine the number and proportion of patients in each arm who experience a complication from an invasive procedure done to investigate an abnormal LCS scan.
5.2.10 Number of diagnosed lung cancers (detected by screening or other) within 16 months of randomization
5.2.11 Whether diagnosed lung cancers were detected incedentally or related to screening
5.2.12 Stage of lung cancers diagnosed
5.2.13 Overscreening: We will determine the proportion of patients with screen diagnosed lung cancer in the mPATH-Lung and control groups who are deemed too ill for potentially curative surgery by blinded chart review.
5.2.14 Reach of digital outreach strategy: Reach of the digital outreach strategy is defined as the proportion of patients who complete the website study eligibility questions. The denominator includes all patients who were sent an invitation, regardless of full program completion and whether or not they were subsequently determined to be eligible for LCS.
5.2.15 Completion of mPATH Lung: Completion of mPATH-Lung is defined as the proportion of patients who complete mPATH-Lung to the point of indicating their screening decision. The denominator includes all patients randomized to mPATH-Lung.

5.3 Exploratory Outcomes

5.3.1 mPATH-Lung Appropriateness: Appropriateness will be measured from the provider's perspective using an emailed survey that includes 8 previously validated appropriateness items.[58]
5.3.2 mPATH-Lung Acceptability: Acceptability of mPATH-Lung will be measured on the post-program survey by the mean of 7 acceptability items drawn from the validated System Usability Scale84 and a previously published

acceptability survey.85 Patients who fail to complete mPATH-Lung will be considered to have found the program unacceptable.

Data Sources

Study Program Database: To determine eligibility for LCS, the study website collects age and smoking history from patients (**Appendix A**). Patients randomized to mPATH Lung also can choose to answer 8 demographic, family history, and medical history items (**Appendix E**) to estimate their personal risk for lung cancer based on a validated model.[14,46] In our pilot testing, 76% of mPATH-Lung users completed these items to obtain this information. Patients randomized to mPATH-Lung will also complete the values clarification exercise to capture their rankings of decision attributes, and will indicate their LCS decision.

*Post-program Survey (**Appendix F**):* Immediately after completing the mPATH-Lung program, all participants will complete a brief self-survey via the study website. The survey will contain 3 program acceptability items drawn from the validated System Usability Scale[60] and a previously published acceptability survey.[61]

*EHR Queries and Chart Reviews (**Appendix G**)*: We will query the EHR in each system to determine if LCS shared decision making clinic visits were scheduled and completed, if LCS was ordered and completed, LCS results (including false positives),and any downstream procedures and complications. One potential marker of overscreening, or screening patients who are unlikely to benefit, is diagnosing early stage lung cancer in patients too ill for surgery. To estimate the impact of mPATH-Lung on overscreening, we will compare the proportion of patients with screen diagnosed lung cancer in the mPATH-Lung and control groups who are deemed too ill for potentially curative surgery by blinded chart review. Given the paucity of LCS programs within North Carolina, it is unlikely that participants would receive screening outside these health networks, and any such “outside screening” should occur equally in both arms, minimizing bias.

Semi-structured Patient Interviews:
We will use qualitative methods to examine situations where initial decisions and subsequent behavior are concordant as well as discordant. Our goals here are to deepen our understanding of how patients’ decisions may evolve over time, and how those changes may be influenced by interactions with providers, family members, or others. We also aim to understand the facilitators and barriers to receiving LCS for those who decide they want screening. We will conduct semi-structured individual interviews with 3 groups of participants reflecting the spectrum of screening decisions and screening behavior.(**Table 3**) All interviews will be conducted after primary data collection is complete to avoid biasing outcomes.

Table 3. Groups for semi-structured interviews (n≥16 per group)

Group	Screening Decision	Screening Behavior
1	Want Screening	Half Screened / Half not Screened
2	Unsure	Half Screened / Half not Screened
3	Decline Screening	Half Screened /

		Half not Screened

Beginning 6 months after the first patient is enrolled, we will review our dataset monthly to identify participants randomized to the mPATH-Lung arm who have completed Aim 1 study involvement in the prior 4 weeks. A research assistant will call these patients to ask if they would be willing to participate in a 45-60-minute interview to discuss their LCS screening decision. Those completing the interview will receive a $75 incentive. Interviews will be conducted by phone at the patient's convenience and recorded for later analysis.

Prior to completing the interview, patients will be asked a series of 7 questions to assess their LCS knowledge. (**Appendix N**) Interviews will be conducting using an interview guide (**Appendix H**). During this interview, we will first ask patients open-ended questions about their screening decision, as well as their current thinking about LCS.. We will then discuss how the patient progressed to complete screening or why they did not. A total of 12 interviews are generally considered sufficient to reach thematic saturation.[62,63] Because half of patients in each group will have completed screening and half will have not, we anticipate we may need a larger sample to reach saturation. Therefore, we will conduct interviews with at least 16 patients in each of the 3 groups shown in **Table 3** (a minimum of 48 interviews).Each interview group will consist of an equal number of patients from each health system. We will analyze the interviews as they are conducted to assess whether saturation has been reached (i.e., no new themes emerged), and will continue recruitment if saturation is not reached.

*Provider Surveys (**Appendix I**):* Following completion of primary data collection, we will invite all primary care providers who had at least one patient randomized to mPATH-Lung to respond to a brief emailed survey that includes portions of a previously validated appropriateness instrument.[58] The survey will also collect basic provider sociodemographic and practice setting characteristics to let us examine how appropriateness varies by subgroups. We will use the Research Electronic Data Capture (REDCap) system, a web-based secure application for building and managing online surveys and databases, for this survey. Within the survey, providers will be informed of the program (purpose, key messages, procedures for lung screening referral)Providers who complete the survey will receive a $10 digital gift card.

*Provider Interviews (**Appendix J**):* The provider survey will reveal *whether* providers find the mPATH-Lung digital outreach strategy appropriate. To gain a deeper understanding of *why* providers' hold their views about the appropriateness of mPATH-Lung, we will conduct 30-minute semi-structured interviews with a subset of at least 24 primary care providers, stratified by clinic network and chosen to reflect a diversity of views on appropriateness. Interviews will be conducted by video call, recorded for later analysis, and scheduled at a time convenient to the provider. The interview guide will explore in greater depth the items assessed on the structured survey (e.g., *why* or *why not* mPATH-Lung seems like a good match for their practice). Additionally, we will explore whether primary care providers perceive patients' ability to self-refer to the lung screening clinic for a shared decision making visit as helpful or harmful and why. Respondents will receive a $50 digital gift card. We estimate that 12 provider interviews in each of the 2 health networks will be sufficient to achieve saturation.[64,65] We will analyze the interviews as they are conducted, and will continue recruitment beyond 12 per health network if saturation is not reached.

6.0 Analytic Plan

6.1 Primary Analysis

The primary analysis will be carried out based on "intent to treat." All patients will be included in their randomized arm whether or not they actually finish the program. The primary objective of effectiveness will be assessed using a logistic regression model with completion of LCS (Y/N) within 16 weeks of enrollment as the outcome, treatment arm as the primary independent variable, and health system as a covariate per the design.

6.2 Secondary Analyses

In secondary analyses of effectiveness, we will assess the effects of age, sex, race and ethnicity, insurance status, and rurality on screening rates using logistic regression models. Additionally, we will conduct separate subgroup analyses for these covariates to obtain estimates and 95% confidence intervals of the intervention effect in these subgroups.

This same strategy described for analysis of completion of LCS to assess the effectiveness of the mPATH-Lung program will be used to assess the impact of the mPATH-Lung program on screening intent, scheduled and completed LCS clinic visits, test ordering, and screening-related harms (including overscreening). For LCS results, we will provide estimates with confidence intervals for the proportion of patients who have Lung-RADS 1 (normal), Lung-RADS 2 (small/stable nodule), Lung-RADS 3 (nodule with 6-month follow-up recommended), and Lung-RADS 4 (concerning nodule needing short-term follow-up or biopsy) results. Ordinal logistic or linear regression will be used to assess the effect of mPATH-Lung on patient knowledge of LCS, depending on the distribution of the outcome. We will also examine knowledge levels in those with a strong preference for or against screening.

We will use descriptive statistics to characterize participants' screening decisions, ratings on the values clarification exercise, most important attributes, and screening behavior. We will use multinomial logistic regression to examine the relationships between the most important attribute and screening decision, where the outcome is coded on three levels (want screening, unsure, do not want screening). We will include the following covariates in the model: age, sex, pack-years of smoking, knowledge score, and 5-year life expectancy (to capture comorbidity) using a previously validated model.[66,67]

We will use descriptive statistics to characterize *Reach* and *Acceptability* by patient sociodemographic characteristics and invitation modality, and the *Appropriateness* by provider and practice characteristics. Similar to our strategy for analyzing our primary outcome, we will use logistic regression to examine the effect of patient characteristics on the *Reach* measures.

Patients will answer the acceptability survey at the end of mPATH-Lung. Each of these 7 items is scored on a 5-point scale from -2 (worst) to +2 (best), and the mean score will define *Acceptability*. Patients who fail to complete mPATH-Lung will be considered to have found the program unacceptable (score of -2). We will use multiple imputation to impute data for participants who complete mPATH-Lung but fail to complete the acceptability survey, which should be rare. Linear regression will be used to determine which patient covariates are associated with *Acceptability*. We will also examine the proportion of patients who view mPATH-Lung as acceptable (scores >= 0), and logistic regression will be used to determine which covariates are associated with *Acceptability*.

Each item on the provider *Appropriateness* survey is scored on a 5-point scale from -2 (worst) to +2 (best). Linear regression will be used to determine which provider and practice characteristics, including number of patients seen in the mPATH-Lung arm, are associated with *Appropriateness*. We will also estimate the proportion of providers who rate mPATH-Lung as appropriate (scores >= 0), and logistic regression will be used to determine which provider and practice characteristics are associated with this outcome.

6.3 Qualitative Analyses

Telephone interviews will be recorded and transcribed verbatim. Transcripts will be reviewed against the original audio for quality control before being imported into Atlas.ti software[68] for coding and data management. Interview transcripts will be paired with individual demographic data and post-program survey responses. We will develop the initial codebook using the interview guide and survey items as a structure. We will then use an inductive approach to modify the initial codebook as new themes emerge. All emergent themes will be discussed amongst the team during the coding process. New codes and definitions will be agreed upon by group consensus. All transcripts

will be dual coded and differences will be discussed and resolved by consensus. Segments of text will be abstracted by code or code combinations and iteratively reviewed/summarized as a team. Themes will be determined by the prevalence and salience in the data.[69] Qualitative outcomes for providers will be compared between the two health networks.

6.4 Sample Size and Power

In 2015 (the year Medicare approved payment for LCS), only 3.9% of eligible Americans were screened.[9] Given that national screening rates are expected to increase, we will conservatively assume the screening rate in the control group will be 10%. A total sample size of 1320 patients (approximately 660 in each group) will provide 90% power for detecting a 6% absolute difference in screening rates at the 5% two-sided level of significance and approximately 80% power for detecting a 5% absolute difference in screening. Because our primary outcome measure is determined by electronic health record review and not surveys, there will be no loss to follow-up.

We anticipate sending approximately 26,000 electronic invitations to identify and accrue 1320 eligible patients. This sample size of 26,000 invitations will allow us to estimate the *Reach* of the electronic invitations to within ±0.6%. Our sample size of 660 patients in the mPATH-Lung arm will allow us to estimate the *Reach* of mPATH-Lung (the proportion of those who complete it) to within ±3.8%. Our sample size of 660 patients in the mPATH-Lung arm will allow us to estimate the mean *Acceptability* score to within ± 0.076 SD. Due to the highly pragmatic nature of this study, our planned sample size will stay 660, but we may over-enroll because it takes time to change the mPATH codebase once accrual targets are reached While we are changing the codebase, participants who received invitations may continue to visit the mPATH web app and be randomized. Therefore, we acknowledge we may over-enroll by a few participants.

Following completion of primary data collection, we will invite all primary care providers who had at least one patient randomized to mPATH-Lung to respond to a brief emailed survey. We expect 466 primary care providers will have at least 1 patient in the mPATH-Lung arm (based on the binomial probability assuming 660 patients in the mPATH-Lung arm and an equal probability of seeing one of 890 health system providers). Based on our prior studies surveying providers (with response rates of 40% - 60%),[38,70] we conservatively estimate 30% will respond which will yield approximately 140 completed surveys. Our sample size of 140 providers will allow us to estimate the mean *Appropriateness* score to within ± 0.17 SD.

6.5 Accrual Rate

In our prior pilot study limited to patients with active portal accounts in a single health system, it required 10 weeks to identify 1000 potentially eligible patients, of whom 35% (349) completed our study program, and 10% (99) were found to be eligible for LCS, yielding 10 patients per week.[1] For this pragmatic trial, we will accrue patients from two health networks and also include patients with cellphone numbers or email addresses, significantly expanding the pool of eligible participants. Patients without portal accounts may be less likely to respond, so we conservatively estimate that we will accrue patients at half the rate (5%) of our pilot study. Therefore, we will send invitations to 260 patients per week (130 at Wake Forest and 130 at UNC) to accrue 13 patients per week, completing accrual over 2 years. We will oversample for non- white patients. We will monitor accrual rates and increase the number of invitations sent as needed.

6.6 Study Timeline

Study Task	Year 1				Year 2				Year 3				Year 4				Year 5			
	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4
Values clarification exercise development and pre-testing	X	X																		
mPATH-Lung program revisions and testing	X	X	X																	
Electronic health record integration and testing			X	X																
Patient/provider survey development and pre-testing			X	X																
Pragmatic trial enrollment (Aim 1)					X	X	X	X	X	X	X	X								
Lung cancer screening outcomes data collection (Aim 1)						X	X	X	X	X	X	X	X	X						
Surveillance tracking of false positives and harms (Aim 1)						X	X	X	X	X	X	X	X	X	X	X	X	X		
Data cleaning					X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Patient interviews about values/drivers of screening decisions (Aim 2)							X	X	X	X	X	X	X	X						
PCP surveys and interviews about mPATH-Lung appropriateness/implementation (Aim 3)														X	X	X				
Data analysis																X	X	X	X	
Results dissemination																	X	X	X	X

7.0 Data Management and Security

All mPATH-Lung interaction data including the embedded self-surveys will be stored on a central Wake Forest data server using industry standard encryption (e.g., AES-256 bit) to protect personal health information. The mPATH-Lung and EHR data will be monitored closely and reviewed at study staff meetings every 2 weeks during enrollment. Quality control information (surveys due/completed, data entered, missing data, out of range data, inconsistent EHR data, etc.) will also be summarized and reviewed, along with accrual rates.

8.0 Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will appear on data collection forms and in study datasets. Any collected patient identifying information corresponding to the unique study identifier will be maintained in a linkage file, stored separately from the data. The linkage file will be kept secure, with access limited to designated study personnel. An honest broker will mediate the electronic health record data queries to limit the exposure of patient identifying information. Because some study outcomes will require a manual chart review (for example, determination of “overscreening”), the honest broker will create a linkage file containing electronic health record numbers that only the study data analyst can access. All personal identifiers (other than dates of service and patient zip code) will be removed from the study datasets and only the study ID included. One year after publication of the main study findings, the linkage file will be destroyed (electronically deleted or shredded in the case of paper forms). Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

9.0 Data Safety and Monitoring

The only anticipated risks specific to this study are loss of data confidentiality. The research team will form an internal Data and Safety Monitoring committee, comprised of the PI, Project Manager, study statistician (Snavely), and study clinical informaticist (Dharod). This committee will monitor the integrity of the study data systems monthly to protect against any security weakness or breaches. The study team will immediately apprise the PI of any problems so that appropriate action can be taken in a timely manner. The PI will promptly review any participant or other-reported concerns regarding the study.

10.0 Reporting of Unanticipated Problems, Adverse Events or Deviations

The PI will report any loss of data confidentiality or other adverse event to the Wake Forest IRB and the NIH within 5 business days of the discovery the event.

Any unanticipated problems, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.

11.0 References

1. American Cancer Society. *Cancer Facts & Figures 2019*. Atlanta: American Cancer Society; 2019.

2. National Cancer Institute Surveillance, Epidemiology, and End Results Program. Cancer Stat Facts: Lung and Bronchus Cancer. SEER. https://seer.cancer.gov/statfacts/html/lungb.html. Accessed February 25, 2019.

3. The National Lung Screening Trial ResearchTeam. Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening. *N Engl J Med*. 2011;365(5):395-409. doi:10.1056/NEJMoa1102873

4. Pinsky PF, Church TR, Izmirlian G, Kramer BS. The National Lung Screening Trial: Results stratified by demographics, smoking history, and lung cancer histology. *Cancer*. 2013;119(22):3976-3983. doi:10.1002/cncr.28326

5. Moyer VA. Screening for Lung Cancer: U.S. Preventive Services Task Force Recommendation Statement. *Ann Intern Med*. 2014;160(5):330-338. doi:10.7326/M13-2771

6. Wender R, Fontham ETH, Barrera E, et al. American Cancer Society lung cancer screening guidelines. *CA Cancer J Clin*. 2013;63(2):106-117. doi:10.3322/caac.21172

7. Jaklitsch MT, Jacobson FL, Austin JHM, et al. The American Association for Thoracic Surgery guidelines for lung cancer screening using low-dose computed tomography scans for lung cancer survivors and other high-risk groups. *J Thorac Cardiovasc Surg*. 2012;144(1):33-38. doi:10.1016/j.jtcvs.2012.05.060

8. Centers for Medicare & Medicaid Services. *Final National Coverage Determination on Screening for Lung Cancer with Low Dose Computed Tomography (LDCT) (CAG-00439N)*.; 2015. https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274. Accessed November 10, 2015.

9. Jemal A, Fedewa SA. Lung Cancer Screening With Low-Dose Computed Tomography in the United States—2010 to 2015. *JAMA Oncol*. 2017;3(9):1278-1281. doi:10.1001/jamaoncol.2016.6416

10. Bach PB, Mirkin JN, Oliver TK, et al. Benefits and harms of ct screening for lung cancer: A systematic review. *JAMA*. 2012;307(22):2418-2429. doi:10.1001/jama.2012.5521

11. Harris RP, Sheridan SL, Lewis CL, et al. The Harms of Screening: A Proposed Taxonomy and Application to Lung Cancer Screening. *JAMA Intern Med*. 2014;174(2):281-286. doi:10.1001/jamainternmed.2013.12745

12. Veronesi G, Maisonneuve P, Bellomi M, et al. Estimating Overdiagnosis in Low-Dose Computed Tomography Screening for Lung Cancer: A Cohort Study. *Ann Intern Med*. 2012;157(11):776. doi:10.7326/0003-4819-157-11-201212040-00005

13. Patz EF. Lung Cancer Screening, Overdiagnosis Bias, and Reevaluation of the Mayo Lung Project. *JNCI J Natl Cancer Inst*. 2006;98(11):724-725. doi:10.1093/jnci/djj226

14. Kovalchik SA, Tammemagi M, Berg CD, et al. Targeting of Low-Dose CT Screening According to the Risk of Lung-Cancer Death. *N Engl J Med*. 2013;369(3):245-254. doi:10.1056/NEJMoa1301851

15. Brenner A, Howard K, Lewis C, et al. Comparing 3 Values Clarification Methods for Colorectal Cancer Screening Decision-Making: A Randomized Trial in the US and Australia. *J Gen Intern Med*. 2014;29(3):507-513. doi:10.1007/s11606-013-2701-0

16. Reuland DS, Cubillos L, Brenner AT, Harris RP, Minish B, Pignone MP. A pre-post study testing a lung cancer screening decision aid in primary care. *BMC Med Inform Decis Mak*. 2018;18(1):5. doi:10.1186/s12911-018-0582-1

17. Flood AB, Wennberg JE, Nease RF, et al. The importance of patient preference in the decision to screen for prostate cancer. *J Gen Intern Med*. 1996;11(6):342-349. doi:10.1007/BF02600045

18. Fagerlin A, Pignone M, Abhyankar P, et al. Clarifying values: an updated review. *BMC Med Inform Decis Mak*. 2013;13(2):S8. doi:10.1186/1472-6947-13-S2-S8

19. Elwyn G, O'Connor A, Stacey D, et al. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *BMJ*. 2006;333(7565):417. doi:10.1136/bmj.38926.629329.AE

20. Edwards A, Elwyn G. *Shared Decision-Making in Health Care: Achieving Evidence-Based Patient Choice*. Oxford: Oxford University Press; 2009.

21. Carter-Harris L, Brandzel S, Wernli KJ, Roth JA, Buist DSM. A qualitative study exploring why individuals opt out of lung cancer screening. *Fam Pract*. 2017;34(2):239-244. doi:10.1093/fampra/cmw146

22. Ali N, Lifford KJ, Carter B, et al. Barriers to uptake among high-risk individuals declining participation in lung cancer screening: a mixed methods analysis of the UK Lung Cancer Screening (UKLS) trial. *BMJ Open*. 2015;5(7):e008254. doi:10.1136/bmjopen-2015-008254

23. Lillie SE, Fu SS, Fabbrini AE, et al. What factors do patients consider most important in making lung cancer screening decisions? Findings from a demonstration project conducted in the Veterans Health Administration. *Lung Cancer*. 2017;104:38-44. doi:10.1016/j.lungcan.2016.11.021

24. Quaife SL, Marlow LAV, McEwen A, Janes SM, Wardle J. Attitudes towards lung cancer screening in socioeconomically deprived and heavy smoking communities: informing screening communication. *Health Expect Int J Public Particip Health Care Health Policy*. 2017;20(4):563-573. doi:10.1111/hex.12481

25. Jonnalagadda S, Bergamo C, Lin JJ, et al. Beliefs and attitudes about lung cancer screening among smokers. *Lung Cancer Amst Neth*. 2012;77(3):526-531. doi:10.1016/j.lungcan.2012.05.095

26. Carter-Harris L, Ceppa DP, Hanna N, Rawl SM. Lung cancer screening: what do long-term smokers know and believe? *Health Expect Int J Public Particip Health Care Health Policy*. 2017;20(1):59-68. doi:10.1111/hex.12433

27. Roth JA, Carter-Harris L, Brandzel S, Buist DSM, Wernli KJ. A qualitative study exploring patient motivations for screening for lung cancer. *PLOS ONE*. 2018;13(7):e0196758. doi:10.1371/journal.pone.0196758

28. Triplette M, Kross EK, Mann BA, et al. An Assessment of Primary Care and Pulmonary Provider Perspectives on Lung Cancer Screening. *Ann Am Thorac Soc*. 2017;15(1):69-75. doi:10.1513/AnnalsATS.201705-392OC

29. Kanodra NM, Pope C, Halbert CH, Silvestri GA, Rice LJ, Tanner NT. Primary Care Provider and Patient Perspectives on Lung Cancer Screening. A Qualitative Study. *Ann Am Thorac Soc*. 2016;13(11):1977-1982. doi:10.1513/AnnalsATS.201604-286OC

30. Rajupet S, Doshi D, Wisnivesky JP, Lin JJ. Attitudes About Lung Cancer Screening: Primary Care Providers Versus Specialists. *Clin Lung Cancer*. 2017;18(6):e417-e423. doi:10.1016/j.cllc.2017.05.003

31. Yarnall KSH, Pollak KI, Østbye T, Krause KM, Michener JL. Primary care: is there enough time for prevention? *Am J Public Health*. 2003;93(4):635-641.

32. Østbye T, Yarnall KSH, Krause KM, Pollak KI, Gradison M, Michener JL. Is There Time for Management of Patients With Chronic Diseases in Primary Care? *Ann Fam Med*. 2005;3(3):209-214. doi:10.1370/afm.310

33. Hobbs FDR, Erhardt L. Acceptance of guideline recommendations and perceived implementation of coronary heart disease prevention among primary care physicians in five European countries: the Reassessing European Attitudes about Cardiovascular Treatment (REACT) survey. *Fam Pract*. 2002;19(6):596-604.

34. Henderson LM, Jones LM, Marsh MW, et al. Opinions, practice patterns, and perceived barriers to lung cancer screening among attending and resident primary care physicians. *Risk Manag Healthc Policy*. 2018;10:189-195. doi:10.2147/RMHP.S143152

35. Simmons VN, Gray JE, Schabath MB, Wilson LE, Quinn GP. High-risk community and primary care providers knowledge about and barriers to low-dose computed topography lung cancer screening. *Lung Cancer*. 2017;106:42-49. doi:10.1016/j.lungcan.2017.01.012

36. Ersek JL, Eberth JM, McDonnell KK, et al. Knowledge of, attitudes toward, and use of low-dose computed tomography for lung cancer screening among family physicians. *Cancer*. 2016;122(15):2324-2331. doi:10.1002/cncr.29944

37. Raz DJ, Wu GX, Consunji M, et al. The Effect of Primary Care Physician Knowledge of Lung Cancer Screening Guidelines on Perceptions and Utilization of Low-Dose Computed Tomography. *Clin Lung Cancer*. 2018;19(1):51-57. doi:10.1016/j.cllc.2017.05.013

38. Lewis JA, Petty WJ, Tooze JA, et al. Low-Dose CT Lung Cancer Screening Practices and Attitudes among Primary Care Providers at an Academic Medical Center. *Cancer Epidemiol Biomarkers Prev*. 2015;24(4):664-670. doi:10.1158/1055-9965.EPI-14-1241

39. Raz DJ, Wu GX, Consunji M, et al. Perceptions and Utilization of Lung Cancer Screening Among Primary Care Physicians. *J Thorac Oncol*. 2016;11(11):1856-1862. doi:10.1016/j.jtho.2016.06.010

40. Carter-Harris L, Tan ASL, Salloum RG, Young-Wolff KC. Patient-provider discussions about lung cancer screening pre- and post-guidelines: Health Information National Trends Survey (HINTS). *Patient Educ Couns*. 2016;99(11):1772-1777. doi:10.1016/j.pec.2016.05.014

41. Brenner AT, Malo TL, Margolis M, et al. Evaluating Shared Decision Making for Lung Cancer Screening. *JAMA Intern Med*. 2018;178(10):1311-1316. doi:10.1001/jamainternmed.2018.3054

42. Volk RJ, Linder SK, Leal VB, et al. Feasibility of a patient decision aid about lung cancer screening with low-dose computed tomography. *Prev Med*. 2014;62(Supplement C):60-63. doi:10.1016/j.ypmed.2014.02.006

43. Housten AJ, Lowenstein LM, Leal VB, Volk RJ. Responsiveness of a Brief Measure of Lung Cancer Screening Knowledge. *J Cancer Educ*. December 2016:1-5. doi:10.1007/s13187-016-1153-8

44. Volk RJ, Bevers TB, Cantor SB. Impact of a patient decision aid on smokers′ knowledge of lung cancer screening harms and benefits: project inform, a randomized controlled trial. Presented at the: 39th Annual North American Meeting, Society for Medical Decision Making; October 23, 2017; Pittsburgh, PA.

45. Bellinger CR, Pinsky P, Foley KL, Case LD, Dharod A, Miller Jr DP. Lung Cancer Screening Benefits and Harms Stratified by Patient Risk: Information to Improve Patient Decision Aids. *Ann Am Thorac Soc*. 2019;16(4):512-514.

46. Dharod A, Bellinger CR, Foley KL, Case LD, Miller Jr DP. The Reach and Feasibility of an Interactive Lung Cancer Screening Decision Aid Delivered by Patient Portal. *Appl Clin Inform*. 2019;10:19-27.

47. Pew Research Center. Mobile Fact Sheet. *Pew Res Cent Internet Sci Tech*. February 2018. http://www.pewinternet.org/fact-sheet/mobile/. Accessed March 5, 2018.

48. Karasz HN, Eiden A, Bogan S. Text Messaging to Communicate With Public Health Audiences: How the HIPAA Security Rule Affects Practice. *Am J Public Health*. 2013;103(4):617-622. doi:10.2105/AJPH.2012.300999

49. Miller Jr DP, Weaver KE, Case LD, et al. Usability of a Novel Mobile Health iPad App by Vulnerable Populations. *JMIR MHealth UHealth*. 2017;5(4):e43. doi:10.2196/mhealth.7268

50. Katki HA, Kovalchik SA, Petito LC, et al. Implications of Nine Risk Prediction Models for Selecting Ever-Smokers for Computed Tomography Lung Cancer Screening. *Ann Intern Med*. 2018;169(1):10-19. doi:10.7326/M17-2701

51. Pinsky PF, Bellinger CR, Miller DP. False-positive screens and lung cancer risk in the National Lung Screening Trial: Implications for shared decision-making. *J Med Screen*. 2018;25(2):110-112. doi:10.1177/0969141317727771

52. Fagerlin A, Zikmund-Fisher BJ, Ubel PA. Helping Patients Decide: Ten Steps to Better Risk Communication. *J Natl Cancer Inst*. 2011;103(19):1436-1443. doi:10.1093/jnci/djr318

53. Hawley ST, Zikmund-Fisher B, Ubel P, Jancovic A, Lucas T, Fagerlin A. The impact of the format of graphical presentation on health-related knowledge and treatment choices. *Patient Educ Couns*. 2008;73(3):448-455. doi:10.1016/j.pec.2008.07.023

54. Hoffman AS, Hempstead AP, Housten AJ, et al. Using a Patient Decision Aid Video to Assess Current and Former Smokers' Values About the Harms and Benefits of Lung Cancer Screening With Low-Dose Computed Tomography. *Med Decis Mak Policy Pract*. 2018;3(1):2381468318769886.

55. Pignone MP, Howard K, Brenner AT, et al. Comparing 3 Techniques for Eliciting Patient Values for Decision Making About Prostate-Specific Antigen Screening: A Randomized Controlled Trial. *JAMA Intern Med*. 2013;173(5):362-368. doi:10.1001/jamainternmed.2013.2651

56. Khan ME. Different Approaches to White Box Testing Technique for Finding Errors. *Int J Softw Eng Its Appl*. 2011;5(3):1-14.

57. European Lung Foundation. Your Lungs and Exercise. http://www.europeanlung.org/assets/files/en/publications/lungs-and-exercise-en.pdf. Accessed March 3, 2019.

58. Weiner BJ, Lewis CC, Stanick C, et al. Psychometric assessment of three newly developed implementation outcome measures. *Implement Sci*. 2017;12:108. doi:10.1186/s13012-017-0635-3

59. Lowenstein LM, Richards VF, Leal VB, et al. A brief measure of Smokers' knowledge of lung cancer screening with low-dose computed tomography. *Prev Med Rep*. 2016;4:351-356. doi:10.1016/j.pmedr.2016.07.008

60. Bangor A, Kortum PT, Miller JT. An Empirical Evaluation of the System Usability Scale. *Int J Human–Computer Interact*. 2008;24(6):574-594. doi:10.1080/10447310802205776

61. Cranney A, O'Connor AM, Jacobsen MJ, et al. Development and pilot testing of a decision aid for postmenopausal women with osteoporosis. *Patient Educ Couns*. 2002;47(3):245-255. doi:10.1016/S0738-3991(01)00218-X

62. Guest G, Bunce A, Johnson L. How Many Interviews Are Enough? An Experiment with Data Saturation and Variability. *Field Methods*. 2006;18(1):59-82. doi:10.1177/1525822X05279903

63. O'Reilly M, Parker N. 'Unsatisfactory Saturation': a critical exploration of the notion of saturated sample sizes in qualitative research. *Qual Res*. 2013;13(2):190-197. doi:10.1177/1468794112446106

64. Saunders B, Sim J, Kingstone T, et al. Saturation in qualitative research: exploring its conceptualization and operationalization. *Qual Quant*. 2018;52(4):1893-1907. doi:10.1007/s11135-017-0574-8

65. Morse JM. The Significance of Saturation. *Qual Health Res*. 1995;5(2):147-149. doi:10.1177/104973239500500201

66. Agrawal A, Mathias J, Baker D, Choudhary A. Five Year Life Expectancy Calculator for Older Adults. In: *2016 IEEE 16th International Conference on Data Mining Workshops (ICDMW)*. ; 2016:1280-1283. doi:10.1109/ICDMW.2016.0184

67. Mathias JS, Agrawal A, Feinglass J, Cooper AJ, Baker DW, Choudhary A. Development of a 5 year life expectancy index in older adults using predictive mining of electronic health record data. *J Am Med Inform Assoc*. 2013;20(e1):e118-e124. doi:10.1136/amiajnl-2012-001360

68. *ATLAS.Ti*. Berlin: Scientific Software Development; 2016.

69. Green J, Thorogood N. *Qualitative Methods for Health Research*. Fourth edition. Los Angeles: SAGE Publications Ltd; 2018.

70. Henderson LM, Marsh MW, Benefield TS, et al. Opinions and Practices of Lung Cancer Screening by Physician Specialty. *N C Med J*. 2019;80(1):19-26. doi:10.18043/ncm.80.1.19