IMPROVING LUNG CANCER SCREENING AND REFERRAL RATES OF NORTH CAROLINA MEDICAID ENROLLEES

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ABSTRACT

BJ Lee Peterson: Improving Lung Cancer Screening and Referral Rates of North Carolina Medicaid Enrollees
(Under the direction of Deborah K. Mayer)

Low-dose chest tomography (LDCT) screening in high-risk patients (individuals age 55-74 with a 30-pack-year smoking history in a current smoker, or similar smoking history in a former smoker who quit within the past 15 years) has proven to reduce both lung cancer and all-cause mortality by 20% and 7%, respectively (Aberle et al., 2011). Despite endorsement by medical and nursing organizations and payers, as well as the strong evidence in support of LDCT screening (Aberle et al., 2011), lung cancer screening rates nationwide remain low at 1.9% (Pham et al., 2018). The goal of this Doctor of Nursing (DNP) quality improvement project was to improve lung cancer screening in eligible Medicaid recipients in a rural primary care practice. The process to improve screening included primary care provider (PCP) education and incorporating a lung cancer risk assessment tool into the practice EHR to assist the PCP to appropriately identify eligible patients for LDCT screening and to increase appropriate LDCT screening referrals. The patient sample included 34 participants who met the USPSTF lung cancer screening eligibility criteria (ages 55-80, documented pack-year smoking history and asymptomatic) from the total Medicaid practice population (N=184) seen during the study period. Data was gathered for three months before and after implementation of the lung cancer risk assessment tool. While our project found no significant improvement in the primary outcome of LDCT screening referral rates in the patient sample, it does provide data on current LDCT referral rates in a high-risk North Carolina Medicaid population. Future practice improvement projects should include educational interventions to increase PCP knowledge of lung cancer screening and process improvements in gathering accurate USPSTF lung cancer screening patient eligibility criteria of pack-years smoking history documentation in the EHR.

Keywords: low-dose chest tomography, LDCT, lung cancer screening

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LIST OF ABBREVIATIONS

ACS	American Cancer Society
AHRQ	Agency for Healthcare Research and Quality
ASCO	American Society of Clinical Oncology
CMS	Centers for Medicare and Medicaid Services
CPT	Current Procedural Terminology
CT	Computed Tomography
CXR	Chest X-Ray/ Chest Radiograph
DANTE	Detection and Screening of Early Lung Cancer by Novel Imaging Technology and Molecular Essays Trial
DLCST	Danish Randomized Lung Cancer CT Screening Trial
DNP	Doctor of Nursing Practice
EHR	Electronic Health Record
HCP	Health Care Provider
IRB	Institutional Review Board
LDCT	Low-Dose Computed Tomography
Lung-RADS	Lung Imaging Reporting and Data System
MILD	Multicentric Italian Lung Detection Trial
NC	North Carolina
NLST	National Lung Screening Trial
NNS	Number Needed to Screen
PA	Physician Assistant
PCP	Primary Care Provider

PDSA	Plan- Do- Study- Act
PHI	Protected Health Information
RCT	Randomized Controlled Trial
SDM	Shared Decision Making
SEER	Surveillance, Epidemiology, and End Results
USPSTF	United States Preventive Services Task Force

CHAPTER 1: INTRODUCTION

Rates of cigarette smoking in North Carolina continue to exceed the national average of (17.9% vs. 16.4%) placing many North Carolinians at risk for developing smoking related lung cancer (National Institutes of Health, 2018). North Carolina Medicaid enrollees, aged 16-64, report much higher smoking rates at 43.3% (State Center for Health Statistics, North Carolina Department of Public Health, 2016). Minorities and those who are socioeconomically disadvantaged (measured by wealth, income distribution, poverty rate, unemployment rate, education, occupation and housing quality) have not only higher smoking prevalence and higher lung cancer incidence, but also higher mortality rates (Singh, Williams, Siahpush, & Mulhollen, 2011). Those with a low socioeconomic status smoke cigarettes more heavily with a duration nearly twice as many years than those with a family income of three times the poverty rate (Siahpush, Singh, Jones, & Timsina, 2009). Socioeconomically disadvantaged patients are more likely to be diagnosed with later-stage cancer and less likely to receive any treatment, surgery, and chemotherapy for lung cancer (Woods, Rachet, & Coleman, 2006).

With 75% of lung cancers in an advanced stage at diagnosis, there is only a 4% five-year survival rate (Siegel, Miller, & Jemal, 2017). Lung cancers can be detected at earlier phases through low-dose computed tomography (LDCT) screening of high-risk patients, a service that is described by some advocates as a "game changer" in the battle against lung cancer (Carter-Harris & Gould, 2017). LDCT screening in high-risk patients (individuals age 55-74 with a 30-pack-per year smoking history in a current smoker, or similar smoking history with quitting within the past 15 years) has proven to reduce both lung cancer and all-cause mortality by 20% and 7%, respectively (Aberle et al., 2011). Despite strong evidence in support of LDCT screening with proven reductions in lung cancer associated morbidity and mortality (Aberle et al., 2011), and the resulting endorsement by medical and nursing organizations and payers, screening rates nationwide remain low at 1.9% (Pham, Bhandari, Oechsli, Pinkston & Kloecker, 2018).

Problem Statement

North Carolina Medicaid enrollees (adults aged 18-64 years, non-institutionalized) report current smoking rates of 43.3%, placing these enrollees at high risk for lung cancer while also being at high risk for healthcare disparities due to their socioeconomic status (State Center for Health Statistics, North Carolina Department of Public Health, 2016). However, LDCT screening guidelines have not been widely implemented into national evidence-based clinical practice as evidenced by a low national lung cancer screening rate of only 1.9% (Pham et al., 2018). Many patient, provider and system level barriers have been suggested as reasons for low screening rates (Carter-Harris & Gould, 2017). There is currently no data published on the estimated or actual numbers of lung cancer screenings in the North Carolina Medicaid population. If the North Carolina Medicaid population does not have access to screening, this gap in care may be contributing to healthcare disparities and poor outcomes.

Purpose

The purpose of this Doctor of Nursing Practice (DNP) practice improvement project is to improve the primary care provider's (PCP's) identification of North Carolina Medicaid enrollees at high risk for lung cancer and appropriately refer for LDCT screening in an effort to detect early-stage lung cancer and decrease lung cancer mortality in a rural community practice.

Background and Significance

Lung cancer statistics. Lung cancer is the third most common cancer and the leading cause of cancer deaths in the United States in both men and women, accounting for one quarter of cancer deaths, and kills more people than breast cancer, prostate cancer, and colon cancer combined. (American Cancer Society, 2019a). The burden of lung cancer in incidence and mortality rates in North Carolina is, on average, higher than that of the United States. Lung cancer was the leading cause of cancer mortality in North Carolina from 2012- 2016 with 27,600 deaths (North Carolina Department of Health and Human Services, 2018). It is estimated that 8,010 North Carolinians will be diagnosed with lung cancer and 5,370 people will die from lung cancer in 2019 (American Cancer Society, 2019b)

Despite improvements in patient survival over the last several decades for other cancer types, including breast and prostate cancer, there have been comparatively marginal improvements in lung cancer survival. The lack of significant improvement in lung cancer survival is largely attributed to the advanced stage at time of diagnosis offering limited treatment options. The national five-year survival rate for lung cancer is 55% when the disease is detected early and still localized within the lungs. However, only 16% of lung cancer cases are diagnosed at an early stage. Unfortunately, lung cancer is primarily detected when the patient has become symptomatic and the cancer has spread to other organs with a five-year survival rate of only 4% (American Lung Association, 2016).

Perhaps the easiest way to improve lung cancer survival is early detection, as suggested by Carbone & colleagues (1970). The earlier lung cancer is detected, the better chance a person has of surviving years after time of diagnosis. The extent of lung cancer in the body, or stage, guides treatment options and influences the length of survival following diagnosis. Nationally, Stage I lung cancer is localized to a primary site (the lung) and represents only 16% of newly diagnosed patients. According to the SEER database, 60% of patients with non-small cell lung cancer and 29% of patients with small cell lung cancer *at a localized (traditionally Stage 1) are alive at five years after diagnosis (American Cancer Society, 2019c).* Twenty-two percent of American lung cancer patients are diagnosed with regional disease, Stages II and III, where the cancer has spread outside of the lung to the lymph nodes, tissues or other organs (National Cancer Institute, 2018). These patients have a 29.7% five-year survival rate. Nationally, approximately 80% of lung cancers are of late stage (Stage IV) at time of diagnosis, conferring poor treatment options and poorer outcomes (SEER, 2018). Fifty-seven percent of patients are diagnosed with distant lung cancer, Stage IV, where the cancer has metastasized and most difficult to treat resulting in five-year survival rates of less than 5% (SEER, 2018). In contrast, North Carolina data on stage of lung cancer at diagnosis is: 18.9% are localized; 24.6% are regional; and 50.1% are distant (North Carolina State Center for Health Statistics, 2017). Currently, stage-specific five-year survival data is not available for North Carolina (American Lung Association, 2019).

Smoking. *It is estimated that* 85-90% of lung cancers are attributable to smoking (Centers for Disease Control and Prevention, 2017a). Despite the declining prevalence of current cigarette smoking among U.S. adults from 20.9% in 2005 to 14.0% in 2017 (Centers for Disease Control and Prevention, 2017b), approximately 42.1 million American adults still smoke cigarettes (Jamal et al., 2014). In 2014, approximately 40% of adult Americans were current or former smokers (Jamal et al., 2014). Clearly, smoking related lung cancer continues to be a major public health problem in the United States and will continue for decades to come.

Mirroring national trends, the smoking rates have decreased overall in North Carolina from 21.8 in 2011 to 17.9 in 2016, yet much more work needs to be done (Centers for Disease Control and Prevention, 2017c). Rates of current cigarette smoking in North Carolina continue to exceed the national average placing many North Carolinians at risk for developing lung cancer (National Institutes of Health, 2018). North Carolina Medicaid smoking rates are higher than for other North Carolinians placing these enrollees at high risk for lung cancer. One study showed that 43.3% of non-institutionalized adults aged 18-64 years enrolled in North Carolina Medicaid reported current smoking compared to 32.2% with no health insurance reported smoking and 16.2% with other health insurance (State Center for Health Statistics, North Carolina Department of Public Health, 2016).

Healthcare disparities. Nationally, adult cigarette smoking has declined from 20.9% in 2005 to 14% in 2017 (Centers for Disease Control and Prevention, 2017a). Smoking rates in North Carolina adults also decreased from 20.9% to 17.2% from 2012 to 2017. However, while adult cigarette smoking rates has decreased overall nationally, there are certain populations where smoking remains high. Those at higher risk include: certain races and ethnicities; young adults; low socioeconomic status; males; living in the South and Midwest; low education; disabled; and lesbian, gay or bisexual individuals (Centers for Disease Control and Prevention, 2017a). While lung cancer is one of the few cancers in which African Americans fare slightly better than white patients in incidence and mortality rates on a statewide level, 53% of cases in African Americans are diagnosed at a distant stage compared to 50% in American Indians, 49% in Whites, and 48% in Hispanics (North Carolina Cancer Prevention and Control Branch/N.C. Comprehensive Cancer Control Program, 2017). The lung cancer incidence rate for American Indians has risen since 1996 more than any other measurable racial or ethnic group in the state

(North Carolina Cancer Prevention and Control Branch/N.C. Comprehensive Cancer Control Program, 2017).

While lung cancer mainly occurs in older people, approximately 30% are less than 65 years of age at time of lung cancer diagnosis (North Carolina Cancer Prevention and Control Branch/N.C. Comprehensive Cancer Control Program, 2017). Of those Americans diagnosed with lung cancer each year, it is estimated that approximately 8% of those are aged 45-54 years old and 22% of those are aged 55-64 years old (North Carolina Cancer Prevention and Control Branch/N.C. Comprehensive Cancer Control Program, 2017). However, most people diagnosed with lung cancer are 65 or older, with 70 years being the national median age at time of diagnosis. While those older than 65 years will qualify for Medicare for insurance coverage, those younger than 65 years may not have health insurance.

Recognition of social determinants of health, disparities, inequities and care gaps are important when evaluating smoking related lung cancer in North Carolina. Poorer overall health, a higher prevalence of comorbid conditions, and greater life stress may also be a function of the challenges Medicaid enrollees face navigating the health care system, including the financial and logistical barriers they encounter when accessing care and historic distrust of a system that's not designed around their needs (Forrest, Adams, Wareham, Rubin, & White, 2013). Medicaid beneficiaries are often in poorer health before their lung cancer diagnosis—making their treatment much more complex. Medicaid or uninsured patients have higher co-morbidity rates with more than a third being obese, approximately 20% being treated for depression, 20% with high blood pressure, and 15% having diabetes (Mendes, 2013).

Socioeconomically disadvantaged patients are less likely to have a usual source of primary care and may face more problems in gaining access to high-quality oncology providers.

There are fewer doctors in North Carolina, with just 139 PCPs per 100,000 people, compared to 154 per 100,000 in the rest of the United States (America's Health Rankings® 2016 Annual Report, 2017). North Carolina invests fewer resources into public health funding ($56 per person) than the rest of the nation ($98 per person)—a difference of nearly $42 (America's Health Rankings® 2016 Annual Report, 2017). More than 72% patients diagnosed with lung cancer between 2010 and 2014 received their primary health insurance through at least one type of governmental program (North Carolina Cancer Prevention and Control Branch/N.C. Comprehensive Cancer Control Program, 2017).

Outcome disparities among low-income populations demonstrate they are at higher risk for poorer treatment outcomes (North Carolina Department of Health and Human Services, 2017). Patients with Medicaid or no insurance consistently have worse outcomes than other patients with lung cancer (Mendes, 2013). These poorer outcomes include higher risks of death than privately insured patients, as well as African-Americans and Hispanics—groups that are disproportionately represented in Medicaid programs—have higher lung cancer incidence and higher lung cancer mortality rates when compared with non-Hispanic whites and those with higher socioeconomic status (Mendes, 2013).

Early detection of lung cancer. Millions of Americans continue to smoke justifying continued investment in widespread smoking cessation efforts. Even if successful, a former smoker still is at increased risk for developing lung or other smoking related cancers. Therefore, uncovering ways to improve lung cancer survival by finding lung cancer at earlier stages of disease is of great importance. Early detection in initial lung cancer screening trials evaluating the use of a variety of tools failed to impact survival outcomes (Oken et al., 2011). Several randomized controlled trials (RCTs) comparing chest radiographs (CXR) with or without sputum cytology conducted prior to the 1990’s failed to show a statistically significant reduction in lung cancer mortality (Wender et al, 2013). As a result, the American Cancer Society removed its initial endorsement for lung cancer screening with CXR for current and former smokers (Wender et al., 2013). However, research continued to evaluate alternative methods, such as LDCT, for early detection of lung cancer. Many of these LDCT randomized clinical trials compared LDCT to CXR with or without sputum cytology with mixed results.

In late 2013, the United States Preventative Services Task Force (USPSTF) issued a Grade B recommendation and endorsed annual LDCT screening in individuals at high risk for developing lung cancer based on the results of the National Lung Screening Trial (Moyer, 2014). High risk is defined as adults aged 55-80 years who have at least a 30 pack-year smoking history and currently smoke or have quit within the past 15 years (USPSTF, 2013). Prior to the USPSTF recommendations and reimbursement of screenings in December 2013, screening rates using LDCT were very low at 3.3% (Jemal & Fedewa, 2017). In 2015, rates had only increased to 3.9% after the Affordable Care Act mandated coverage of LDCT screening for high-risk privately insured individuals. The Centers for Medicare and Medicaid Services (CMS) initiated coverage for LDCT in February 2015 for eligible persons with a written prescription and shared decision-making (SDM) documentation (Simmons, Gray, Schabath, Wilson & Quinn, 2017). Professional organizations such as the American Cancer Society (ACS) and American Society of Clinical Oncology (ASCO) also supported adoption of LDCT screening in high-risk populations. Medicaid coverage of lung cancer screening was deferred to the individual states.

Two years after these recommendations and national support for lung cancer screening, rates remained low despite the evidence that screening reduces lung cancer mortality. The lack of screening means that only 262,700 of the eligible 6.8 million high-risk Americans were evaluated for lung cancer despite the potential to thwart thousands of deaths annually (Jemal & Fedewa, 2017). In the first national estimate of LDCT screening following the USPSTF recommendation in 2015, over 50% of smokers meeting USPSTF criteria for LDCT screening were Medicaid or uninsured (Jemal & Fedewa, 2017). While this study was not designed to evaluate reasons for low uptake of LDCT screening, the authors proposed that reasons may include gaps in smoking knowledge regarding LDCT, lack of access to care, and lack of physician's knowledge about screening recommendations and reimbursement (Jemal & Fedewa, 2017).

A more recent publication showed that annual LDCT screening remains inadequate following USPSTF recommendations despite the time since implementation and potential to prevent thousands of lung cancer deaths each year (Pham et al., 2018). This study showed that in 2016, only 1.9% of 7.6 million eligible smokers were screened by LDCT for lung cancer. While the aim of this study was to update the number of LDCTs performed in the United States, the author speculated that reasons may range from lack of physician knowledge and referral, to lack of patient interest in and knowledge of screening (Pham et al., 2018).

An important link between the high-risk patient and the LDCT screening center is the PCP. The PCP most often represents the initial point of coordination of preventative care in the United States and where most cancer screening occurs opportunistically instead of through a specific organized screening program. The PCP is well-positioned to assist the patient with decision-making for lung cancer screening interventions. A study by Klabunde et al. (2012) evaluated PCP lung cancer screening practices in the United States. This suggested improved education around existing barriers to screening identified by the PCP (evidence of LDCT, guidelines, potential harms, and costs) could address gaps in PCP LDCT knowledge.

Review of Literature

The potential improvements in lung cancer and all-cause mortality and earlier stage at diagnosis with LDCT screening of a high risk patient population necessitates a review of the literature to more fully evaluate the benefits of lung cancer screening with LDCT. Searches were conducted in CINAHL, PubMed and Embase (Appendix A). The combined search terms included: (1) lung cancer screen*; AND (2) LDCT OR low dose chest tomography; AND (3) nurs* OR nurse practitioner OR physician assistant OR primary care OR family OR physician. Limitations on search terms included: language (English); publication years (5 years or 2012-2017) plus known landmark studies; and age (middle aged+: 45 + years, middle aged: 45-64 years, aged: 65+ years; and 80 and over or very elderly: 80+ years). The search terms were all combined to yield 22 results in PubMed, six in CINAHL, and 32 in Embase. The addition of the search term "practice change" yield no results in any of the databases. Forty-three articles were reviewed. Of these results, four RCTs of LDCT screening were selected for inclusion in the review of literature as they were the only studies reporting results of both the intervention (LDCT) and control (non-LDCT) groups (Appendix B).

Results and Discussion

Of the four RCTs included in the review, only the National Lung Screening Trial (NLST) compared annual LDCT to annual CXR (Aberle et al., 2011). In the largest high quality LDCT screening trial to date, the U.S. based, multicentered NLST enrolled 53,454 participants. Eligible participants were between the ages of 55-74 and current or former smoker (quit $\leq$15 years ago) with $\geq$30 pack year smoking history. Participants received three annual scans.

The three remaining trials compared screening with LDCT to annual clinical review or usual care. Sample sizes varied among these trials, as did enrollment eligibility. In contrast to the NLST, the DANTE trial (Infante et al., 2009) enrolled 2472 participants comparing LDCT to annual clinical review. This Italian study of three hospitals from the same network evaluated asymptomatic men between the ages of 60-74 who were current or former smokers with >20 pack-year smoking history. The DLCST trial (Saghir et al., 2012) randomized 4104 men and women at a single site in Denmark. Participants were between the ages of 50-70 and current and former smokers (<10 years and > 4 weeks since smoking cessation) with ≥20 pack-year smoking history. The MILD trial (Pastorino et al., 2012) evaluated LDCT (annual versus biennial) compared to usual care. This single institution trial conducted in Milan enrolled 4099 participants. Current and former smokers, at least 49 years of age with no upper age limit, with a ≥20 pack-year smoking history or quit ≤10 years ago were eligible for study participation.

Lung cancer mortality. Clinical trial findings on lung cancer associated mortality were described in three of the four RCTs (Aberle et al., 2011; Infante et al., 2009; Saghir et al., 2012). The NLST reported a 20% reduction in lung cancer mortality with LDCT (95% CI, 6.8-26.7; p = 0.004). The study authors reported a number needed to screen (NNS) with LDCT to prevent one lung cancer death of 320 (among those undergoing ≥1 screens). This is compared to screening 900-1900 all-comers requiring screening mammograms to prevent one death from breast cancer, and screening 500 individuals with colonoscopy to prevent one death from colorectal cancer (Humphrey et al., 2013). Three trials comparing LDCT to annual clinical review or usual care reported lung cancer mortality rates that were not statistically different between randomized groups.

All-cause mortality. The NLST (Aberle et al., 2011) found a 6.7% reduction in all-cause mortality between those in the LDCT group and those in the CXR group (95% CI, 1.2-13.6, p = 0.02). The calculated NNS to prevent one death from any cause was 219 (95% CI, 112- 5,000). In contrast, the three trials comparing LDCT to annual clinical review or usual care showed no difference in all-cause mortality rates (Infante et al., 2009; Saghir et al., 2012; Pastorino et al., 2012).

Lung cancer-specific and all-cause mortality rates were only statistically significant in the NLST (Aberle et al., 2011) among the trials evaluated. There are differences between these trials that may have influenced these findings. The sample sizes among the four trials were quite different. The NLST had a large sample size of 53, 454 persons enrolled, compared to 2472 enrolled in DANTE, 4104 enrolled in DLCST, and 4099 enrolled in MILD (Aberle et al., 2011; Infante et al., 2015; Saghir et al., 2012, Pastorino et al., 2012). There was likely not enough power in the DANTE, DLCST and MILD trials to find significant differences in lung cancer mortality and all-cause mortality rates. The number of LDCT scans performed varied among the four trials, ranging from three annual LDCT scans in the NLST (Aberle et al., 2011) to five annual scans in both the DANTE and DLCST (Infante et al., 2015; Saghir et al., 2012). Median time of follow-up also varied among the four trials. The NLST (Aberle et al., 2011) followed patients for a median of 6.5 years. This compares to the shorter durations in DANTE (Infante et al., 2015) where the median follow-up was 2.9 years for the intervention group and 2.6 years for the control group; DLCST (Saghir et al., 2012) median follow-up was 4.8 years; and MILD (Pastorino et al., 2012) median follow-up was 3.8 years for the LDCT group and 4.7 years for the control group. This difference in follow-up may impact the power of the studies to show a benefit. The number of average pack-year smoking history also varied among the trials. Lung cancer incidence rates in the NLST and DANTE trial were higher than in the DLCST and MILD studies and is likely a reflection of more smoking exposure placing them at significantly higher risk of lung cancer. The NLST (Aberle et al., 2011) reported the highest mean smoking history of 56 pack-years; DANTE (Infante et al., 2015) reported mean smoking history of 47 pack-years; DLCST (Saghir et al., 2012) reported mean smoking history of 36 pack-years; and MILD (Pastorino et al., 2012) reported mean smoking histories of 38 and 39 pack-years.

Stage at diagnosis. All four studies in the review reported a positive impact of screening on early stage at diagnosis compared with CXR, annual clinical review, or usual care. The NLST (Aberle et al., 2011) reported 51.8% (329 of 635) Stage 1A and 11.2% (71 of 635) Stage 1B lung cancers in the LDCT group compared to 32.7% (90 of 275) Stage 1A and 14.9% (41 of 275) Stage 1B lung cancers in the CXR group which was a significant difference. DANTE (Infante et al., 2015) reported significantly more Stage 1 lung cancers in the LDCT group (53 of 63, 84%) compared to the control group (12 of 35, 34%; $p = 0.004$). DLCST (Saghir et al., 2012) reported more early stage cancers (Stage 1 and 2) in the LDCT group compared to the control group (54 vs. 10, $p < 0.001$). The MILD trial (Pastorino et al., 2012) reported 59% Stage 1A lung cancers in the annual LDCT arm vs. 55% in the biennial arm vs. not reported in the control arm.

The results from these four RCTs support LDCT screening as an effective method to detect cancers at an earlier stage of lung cancer diagnosis when conducted in similar patient populations and under similar clinical trial conditions. The earlier stage at time of lung cancer diagnosis leads to more treatment options available to the patient and subsequent improvements in lung cancer mortality.

Systematic reviews of lung cancer screening with LDCT since the publication of the NLST have assessed the risks versus benefits of LDCT (Bach et al., 2012; Gopal, Abdullah, Grady & Goodwin, 2010; Humphrey et al., 2013; Manser et al., 2013; Slator, Sullivan, Pappas & Humphrey, 2014; Usman et al., 2016). The identified harms associated with LDCT lung cancer screening include false-negative results, false-positive results, incidental findings, overdiagnosis, radiation exposure, and psychological distress (Moyer, 2014). The harms of false-negative results were not studied in the reviews. However, the sensitivity of LDCT for detecting lung cancer ranged from 80-100%, implying a false-negative rate of 0-20% (Humphrey et al., 2013). False-positive results ranged from 9.2-51% of participants in baseline screens, with positive predictive values for abnormal studies ranging from 2.2-36%. Most abnormal LDCT scans were resolved with further imaging. Positive examinations were lower in subsequent follow-up screens, with positive predictive values for abnormal studies ranging from 4-42%. Positive predictive values for abnormal LDCT scans with recommendations for biopsy ranged from 50-92% (Humphrey et al., 2013).

There were no standardized approaches to reporting incidental findings among the studies. In LDCT studies, non-pulmonary findings of infections, other types of cancer and coronary artery calcification were commonly reported (Humphrey et al., 2013). Overdiagnosis was not formally reported in the studies. However, four RCTs of LDCT which reported results in both the LDCT and no LDCT groups suggested overdiagnosis in only one trial showing an excess of 119 lung cancers among 26,722 participants after 6.5 years of follow-up (Humphrey et al., 2013). Radiation associated with one LDCT scan ranged from 0.61 to 1.5 mSv in two RCTs and two cohort studies reported. LDCT screening produces similar radiation exposure to mammography screening (United States Preventative Services Task Force, 2013). Only one study reported cumulative radiation exposure associated with the LDCT screening program, which was estimated at 6 to 7 mSv (Humphrey et al., 2013). Most studies reported no long-term differences in psychological distress among groups, but there was some evidence to suggest increased short-term anxiety among those with positive or intermediate findings (Humphrey et al., 2013).

In summary, evaluation of the current evidence affirms the need for continued development of standardized practices and guidance for not only the LDCT screening procedure, but also for follow-up testing to amplify accuracy, determine cost-effectiveness and reduce harms. LDCT screening has proven to be an effective method to detect cancers at an earlier stage of lung cancer diagnosis leading to more available treatment options to the patient and subsequent improvements in lung cancer mortality. However, patient, provider and system level barriers have been suggested as barriers to widespread adoption (Carter-Harris & Gould, 2017).

Barriers to lung cancer screening. Several studies have identified limited understanding of screening guidelines and LDCT effectiveness in lung cancer screening by PCPs as key barriers to appropriate screening referrals (Simmons et al., 2017; Lewis et al., 2015; Ersek et al., 2016; Klabunde et al., 2012). These studies also indicate that a majority of PCPs would recommend LDCT screening to their high-risk patients if they had more information. Additional commonly identified barriers to recommendation of screening include perceptions about patient costs, potential harms from false positives, patient lack of awareness, risk of incidental findings requiring additional evaluation, risk of radiation exposure, patient stress and anxiety, and lack of insurance coverage. Some of these studies also indicated that despite discussing the risks and benefits of lung cancer screening with their high-risk patients, many PCPs made no screening recommendations. Additionally, physicians were more likely to order screening when they believed national expert organizations recommend lung cancer screening, when they perceive the screening test to be effective, and when high-risk patients ask about lung cancer screening.

The majority of PCPs in these studies identify early detection as the main benefit of LCDT screening (Simmons et al., 2017; Ersek et al., 2016); however, a low proportion believe that LDCT actually reduced lung cancer mortality (Ersek et al., 2016; Lewis et al., 2015). Primary care providers who believe that LDCT screening reduces mortality in the high-risk population are more likely to believe that screening and early detection has the potential to improve quality of life, improve overall outcomes, and motivate smoking cessation (Simmons et al., 2017). In fact, Ersek and colleagues (2016) reported in the evaluation of the knowledge of, attitudes toward, and use of LDCT for lung cancer screening among family physicians that: 98% felt LDCT increased odds of detecting cancer at an earlier stage; 75% felt the benefits outweighed the harms; 76% discussed risks/benefits of LDCT in some capacity with their patients; yet >50% reported making one or no screening recommendations in the past year.

Additionally, Lewis and colleagues (2015) assessed lung cancer screening practices and attitudes among PCPs in the era of new LDCT screening guidelines at an academic medical center. The investigators found that few PCPs ordered lung cancer screening with approximately 50% of the PCPs knowing three or more of the six guideline components for lung cancer screening (screen annually; begin screening at age 50 or 55; end screening at age 75 or 80; 20 or 30 pack-years smoking history; current and former smokers; and not exposure to secondhand smoke only), and 24% knew none of the screening components. This study showed that PCPs had a limited understanding of lung cancer screening guidelines and LDCT effectiveness with these knowledge gaps hindering the uptake of evidence-based lung cancer screening guidelines.

In North Carolina, there is lack of information among health care providers (HCPs) regarding the process for coverage for North Carolina Medicaid enrollees meeting eligibility criteria for lung cancer screening (P. Rivera, personal communication, August 29, 2018). Many

HCPs involved in the development and management of lung cancer screening clinics throughout the state continue to voice concerns over North Carolina Medicaid requests for coverage being denied for eligible high-risk patients (S. Skibo, personal communication, August 18, 2018). Most providers state confusion around the state's administration of the CMS mandate to cover LDCT screening (L. Bowlby, personal communication, January 26, 2018). Online resources regarding North Carolina Medicaid coverage for lung cancer screening are difficult to locate. Key North Carolina lung cancer screening thought leaders have little knowledge of the prior authorization requirement through the vendor, EviCore, with none reporting familiarity with this requirement or guidelines (P. Rivera, personal communication, August 29, 2018). Currently, North Carolina Medicaid covers chest computed tomography (CT) without contrast under the current procedural terminology (CPT) code of CPT 71250 but not the usual LDCT lung screening code of G0297. This creates a significant problem because this CPT code for chest CT does not require reporting findings in the consistent screening language of Lung-RADS (P. Rivera, personal communication, August 29, 2018). Lung-RADS was created to standardize lung cancer screening CT reporting and management recommendations, reduce confusion in lung cancer screening CT interpretations, and facilitate outcome monitoring (American College of Radiology, 2018). Given that CPT 71250 must be used to gain prior authorization for lung cancer screening in high risk Medicaid patients, inaccurate data collection on the number of LDCT screenings conducted in the North Carolina Medicaid population are likely occurring.

Lung cancer screening is the first cancer screening to require a shared decision making (SDM) component for reimbursement by CMS (Carter-Harris, Tan, Salloum, & Young-Wolff, 2016). Shared decision making is collaborative communication, which occurs between a patient and provider where the patient is the focus of care and the patient's values regarding medical decisions are considered (Delbanco & Gerteis, 2015). The USPSTF outlines the content of the SDM conversation, which should occur prior to actual LDCT screening: advantages, limitations, known harms and potential harms (Moyer, 2014). Billing code G0296 is utilized to document the SDM process.

Despite PCPs recommending traditional cancer screening (such as mammography for breast cancer; pap smears for cervical cancer; and fecal occult blood, flexible sigmoidoscopy and colonoscopy for colorectal cancer), LDCT screening is not yet included in the PCP's daily practice recommendations (Ersek et al., 2016). Ersek and colleagues (2016) called for increased provider educational outreach to improve screening rates. By improving PCP knowledge of commonly identified barriers (lung cancer screening's evidence base, guidelines, potential harms, and reimbursement) and reinforcing the confirmed benefits, lung cancer screening can be enacted to improved lung cancer mortality.

Theoretical Framework

The importance of using science-based concepts to evaluate and enhance health care delivery and improve patient outcomes is critical to evidence-based practice. Equipping the clinician to appropriately discuss risks and benefits and refer high risk patients for lung cancer screening and to discern how to best disseminate and implement this knowledge should be informed by evidence rather than opinion or belief.

Rogers' Diffusion of Innovations Theory (1962) has been used to examine research utilization in many disciplines, and may offer insights to the diffusion of ideas and practices related to guideline recommended lung cancer screening among clinicians. Rogers' theory suggests that when the individual perceives information as new knowledge or evidence ("innovation"), the reaction to the innovation determines how that individual will begin to adopt the new idea. Utilizing Roger's theory as a guiding framework for targeted educational efforts and implementation of a lung cancer risk screening tool can improve evidence-based practice and patient outcomes.

Rogers' theory is a group of ideas that provide a description and explanation of the phenomenon by which new ideas, products, or behaviors spread over time throughout a society or organization (Nilsen, 2015). The result of this diffusion is the adoption of the idea, product or behavior as part of the social system. The key to adoption is the perception of this idea, product or behavior as new or innovative. Interpersonal influence of opinion leaders or change agents, and the adoption decisions of targeted individuals are the keys to spreading the innovation (Greenhalgh, Robert, Macfarlane, Bate & Kyriakidou, 2004).

Rogers (1962) described five adopter classifications on the basis of innovativeness (innovators, early adopters, early majority, late majority and laggards). The rate of adoption is the relative speed with which the members of the social system adopt an innovation and early adopters have different characteristics than those who are slower to adopt. The new idea or innovation is communicated through successive diffusion stages over a period of time to members of the social system (Rogers, 2002). This diffusion may be passive or active. Rogers also describes five process factors that influence the rate of adoption: knowledge, persuasion, decision, implementation and confirmation. These major components of Rogers' theory will inform the process of diffusion and dissemination of lung cancer screening education and screening tool within the practice site with the aim to increase referrals for LDCT in high-risk individuals.

When Rogers' theory is applied to evidence-based lung cancer screening recommendations in clinical practice, the goal is to guide the spread of research to address the identified knowledge or behavior gap in targeted clinicians' practices (Greenhalgh, Robert, Macfarlane, Bate & Kyriakidou, 2005). The PCP is well positioned to assist the patient with decision-making for preventative screening interventions as they represent the initial point of care coordination of preventative care in the United States. Studies have identified the PCP's lack of knowledge of lung cancer screening (Simmons et al., 2017), lack of knowledge of guidelines (Lewis et al., 2015), and lack of knowledge of payment and reimbursement (Ersek et al., 2016) as key barriers to appropriate screening. Reinforcing the confirmed benefits of and improving PCP knowledge of barriers to screening can lead to improved lung cancer mortality through earlier detection. The diffusion of innovation theory may prove a beneficial framework to efficiently spread this evidence-based research knowledge into clinical practice.

According to Rogers' theory, when promoting an innovation such as lung cancer screening, it is important to understand the characteristics of the target population that will assist or hinder the adoption into practice. Rogers contends there are five established adopter categories with different strategies useful in appealing to the different adopter categories. Knowing that most clinicians in the implementation site will fall into the middle categories of early adopters, early majority, and late majority, providing strategies (such as success stories and evidence of success) to appeal to these providers will be important to adoption of the lung cancer screening initiative.

Adoption of an innovation by an individual is a process rather than a single event and is often dependent upon other decisions within an organization (Rogers, 2003). The rate of innovation diffusion is related to the five attributes of the innovation: (1) the adopter's perception of the relative advantage of the innovation; (2) the compatibility of the innovation with existing structures; (3) the perceived degree of difficulty involved in adopting the innovation; (4) the testability of the innovation, in the absence of significant resources; and (5) the visibility of outcomes resulting from adoption of the innovation (Rogers, 1995).

The five-step innovation-decision process of individual stages by which a person adopts an innovation includes: knowledge, persuasion, decision, implementation, and confirmation. If the innovation has greater relative advantage to the one it is to replace, and if the innovation is consistent with existing beliefs, values, past history and practice needs, the adoption will occur more quickly. If the innovation is easy to understand and use and is of low complexity, it will be adopted sooner. If the innovation can be piloted to see its advantages, and it is observable and seen by others in the social system considering adoption, it will likely diffuse more rapidly.

This project will address the identified key barriers to practice implementation, which will be targeted toward the informational needs at the practice site (such as the closest certified LDCT screening location, requirements for referral, reimbursement, and processes for both SDM conversations and follow up of abnormal findings). The use of a simple lung cancer risk screening tool embedded into the practice electronic health record (EHR) which is relatively quick and easy for the PCP to identify the at-risk patient is of great importance. A pilot of the screening tool will be conducted with intended users prior to formal launch of the tool to assess gaps in future implementation.

There are three identified types of innovations knowledge: awareness knowledge, how-to knowledge, and principles knowledge. Studies have shown that the majority of potential adopters do not base their decision on scientific studies, but prefer to receive subjective information from a peer within their social system. When considering implementation of the lung cancer risk screening tool, using an early adopter influencer from within the social system to provide information and support will be key in communicating the benefits of screening.

Limitations of Rogers' theory include the fact that although the S-shaped curve and the adopter categories were originally developed as a descriptor model, it cannot explain how or why people adopt innovations at different rates or if adoption will be successful (Greenhalgh et al., 2005). Rogers' theory does not promote an active participation in adoption of the innovation, which newer research has found to be more effective in individual behavior change. One review found that more active interventions, such as HCP reminders and educational outreach, were more effective in changing provider behavior than passive interventions (Ellis et al., 2005).

Rogers' theory serves as a necessary schema for translating evidence-based lung cancer screening guidelines into clinical practice to effectively and efficiently improve health outcomes in patients at high risk of lung cancer. Lung cancer screening initiatives must be perceived as not only advantageous with low implementation complexity, but also readily adaptable with clear advantages in order to promote its adoption into clinical practice. Without the guiding framework of Roger's diffusion of innovation theory, there would be a lack of understanding of both the engagement of potential adopters of lung cancer screening at the proposed clinical site and the innovation-decision process and possible obstacles to adoption. A lack of understanding of the patterns of adoption by individuals could potentially lead to unsuccessful implementation of the lung screening education and tool due to the lack of utilization of key opinion leaders to influence the behavior of potential adopters.

Rogers' Diffusion of Innovations Theory provides understanding of the complexities involved in the process of adopting new ideas and practices, such as the evidence-based care practice of lung cancer screening in high-risk adult populations. Rogers' theory can serve to not only identify, but also direct efforts at individual and organizational levels to facilitate lung cancer screening adoption. Several studies have demonstrated improvements in process measures such as knowledge but failed to demonstrate changes in individual provider behavior (Raz et al., 2018). This practice change project aims to increase lung cancer screening rates by translating this new knowledge into behavior change.

LDCT screening guidelines have not been widely implemented into national evidence-based clinical practice (Pham et al., 2018). Many patient, provider and system level barriers have been suggested as reasons for low screening rates (Carter-Harris & Gould, 2017). Despite North Carolina Medicaid enrollees reporting current smoking rates of 43.3%, placing these enrollees at high risk for lung cancer while also being at high risk for healthcare disparities due to their socioeconomic status (State Center for Health Statistics, North Carolina Department of Public Health, 2016), current lung cancer screening rates in this population are not known. Can implementation of a lung cancer screening assessment tool into a rural community practice EHR improve PCP's identification of North Carolina Medicaid enrollees at high risk for lung cancer and increase appropriate referrals for LDCT screening?

Study Outcomes

The primary outcome of this study was to evaluate change in primary care provider behaviors in LDCT screening referrals (number who were eligible and referred for LDCT screening, number who were eligible and not screened, and number who were eligible but refused LDCT referral) following provider education and implementation of a lung cancer risk assessment tool. Secondary outcomes included collection of descriptive data regarding the total Medicaid practice sample cohort in addition to the patient sample for LDCT referral cohort before and after implementation of the project.

CHAPTER 2: METHODS

The goal of this DNP quality improvement project was to improve lung cancer screening in eligible North Carolina Medicaid recipients. The process to improve screening included incorporating a lung cancer risk assessment tool into the practice EHR to assist the PCP to appropriately identify eligible patients for LDCT screening to increase appropriate LDCT screening referrals.

Setting and Participants

Site implementation was conducted at a busy family practice in rural Vance County, North Carolina. The office has four physicians and 11 physician assistants caring for patients. The investigator worked closely with a Physician Assistant (PA), who serves as lead for quality practice improvement projects and liaison between the investigator and key personnel at the practice site. The practice site has an electronic medical record (AllScripts), which is well-incorporated into daily clinic practice.

According to North Carolina County Rankings, Vance County ranks 14th in lung cancer mortality rate of 59.8 per 100,000 (2011-2015) compared to North Carolina mortality rate of 49.0 per 100,000 (North Carolina Cancer Prevention and Control Branch/N.C. Comprehensive Cancer Control Program, 2017). Vance County also ranks 18th in distant stage at diagnosis (2010-2014), and 1st in current smoking rates (2012) (North Carolina Cancer Prevention and Control Branch/N.C. Comprehensive Cancer Control Program, 2017). In fact, Vance County reports percentage of current smokers at 29%, which outpaces North Carolina's overall percentage of 21% (North Carolina Cancer Prevention and Control Branch/N.C. Comprehensive Cancer Control Program, 2017). Additionally, Vance County is among the six North Carolina counties with the highest percent of people enrolled in NC Medicaid as of January 2017, ranging between 32-40% (Toledo, 2017). North Carolina Medicaid smoking rates are higher than for other North Carolinians placing these enrollees at high risk for lung cancer. The State Center for Health Statistics, North Carolina Department of Public Health (2016) conducted a study, which showed that 43.3% of non-institutionalized adults aged 18-64 years enrolled in North Carolina Medicaid reported current smoking.

Design and Data Collection

This practice change project was designed to aid the adoption of evidence supported lung cancer screening into primary care clinical practice by incorporating a lung cancer risk assessment tool into the existing EHR to facilitate providers screening and referral. Data was gathered for three months before and after implementation of the lung cancer risk assessment tool in order to evaluate the impact on provider lung cancer screening behavior.

As lung cancer screening is complex, the review of the literature has emphasized that education of the provider is important in lung cancer screening and was provided prior to implementation of the screening tool (Simmons et al., 2017; Lewis et al., 2015; Ersek et al., 2016; Klabunde et al., 2012). A 15-minute education session with providers was delivered in conjunction with a PowerPoint presentation (Appendix C) addressing national, state and county specific lung cancer statistics, LDCT screening benefits and risk, USPSTF guideline recommendations, review of the Agency for Healthcare Research and Quality (AHRQ) decision aid tool (“Is Lung Cancer Screening Right for Me: A Decision Making Tool for You and Your Clinician” and “Lung Cancer Screening: A Clinician’s Checklist”), review of the SDM conversation and documentation, overview of North Carolina Medicaid coverage requirements, coding and prior authorization process, and overview of the resource/ referral guide. For those providers unable to attend the education session, the PowerPoint presentation was emailed to them for review. The PowerPoint was also emailed out to all practice HCPs for their reference. The site quality improvement lead informed office and nursing staff of the procedure of documenting information for the eligible patients' visits. No letters or phone calls were made to proactively recruit patients to for LDCT screening assessment. Patients were evaluated as they presented for a scheduled appointment to more closely represent a PCP office without staff dedicated to a lung cancer screening program.

Upon registration at the clinic on the day seen, patients who were North Carolina Medicaid enrollees (single coverage or dual eligible), age 55-80 years, and had a documented smoking history in the EHR were identified as eligible for participation (Appendix D) and were given a "Is Lung Cancer Screening Right for Me: A Decision Making Tool for You and Your Health Care Professional" (Appendix E) form from a tear-pad kept at the check-in desk to complete while waiting in the lobby for their appointment. If the front office personnel missed handing the form to the patient at check in, the medical assistant/ nursing staff were to provide this tear-pad form to the patient for completion while waiting in the room for the PCP. The form was to then be handed to the PCP by the patient and the information would be reviewed together to calculate the pack year history and assess the patient's risk for lung cancer, undergo a SDM conversation, provide smoking cessation counseling if needed, and refer for LDCT screening if appropriate.

Demographic and outcomes data was extracted from the clinic EHR system. Data on zip code to determine rural versus urban living address, race/ ethnicity, gender and age were collected to describe the population. No protected health information (PHI) was collected. Outcomes data included use of codes G0297 (LDCT screening) and CPT 71250 (diagnostic CT). The actual chart was reviewed if the patient was eligible for LDCT screening but referral was not ordered or if the patient refused LDCT screening referral. Data were entered into an excel spreadsheet. The clinic's EHR could not be altered to allow for discreet fields for documentation of the seven questions to assess the risk of lung cancer for North Carolina Medicaid enrollees. Therefore, the decision was made to embed a .pdf of the seven questions into the EHR (Appendix G). Upon a North Carolina Medicaid enrollee with smoking history presenting to the clinic, documentation of patient aged 55-80 years triggered subsequent screening questions consistent with NC Medicaid lung cancer screening criteria (EviCore, 2018). These questions in the .pdf tool included:

1. Is the patient between 55-80 years of age? Yes/No
2. Calculate pack-years smoking history with formula: number of years smoked x average number of packs smoked per day = pack years ___ Number
3. Does the patient have at least a 30 pack-year history of cigarette smoking? Yes/ No
4. Does the patient currently smoke or quit less than 15 years ago? Yes/ No
5. Is the patient asymptomatic of underlying lung cancer symptoms? Yes/No
6. Is the patient willing to undergo curative lung surgery? Yes/ No
7. Has the patient receive a low-dose CT lung screening in less than 12 months? Yes/ No

It is important to mention that none of these questions, including smoking pack year history, were mandatory ("hard stops") for completion by the clinician or clinic staff. Due to the risk of provider "pop-up fatigue," electronic pop-up reminders were not utilized in this project.

If the patient met all North Carolina Medicaid criteria for high risk of lung cancer, the provider then entered into a SDM conversation with the patient reviewing the benefits and risks of LDCT lung cancer screening followed by smoking cessation and smoking abstinence counseling, if needed. This SDM visit included review of the decision aid titled "Is Lung Cancer Screening Right for Me?" developed and published by AHRQ. The provider then documented the SDM discussion and decision. If the patient met all criteria and chose to receive LDCT referral for screening, a written order for the lung cancer screening visit with required information was generated from the EHR. As currently is the practice, the Department of Radiology continued to perform prior authorization prior to the LDCT scan. If the patient declined LDCT screening, the rationale for that decision was to be documented in the EHR. If the patient was unsure about referral for LDCT screening or requests more time, the patient was to be scheduled for a follow-up clinic visit to discuss the screening decision. Documentation of a smoking cessation and abstinence counseling session continued to be required for all patients who were currently smoking.

Baseline chart review of three months prior to implementation (October 19, 2018 through January 18, 2019) determined the number of North Carolina Medicaid enrollees aged 55-80 years of age who were current or former smokers and eligible for LDCT screening assessment.

Following the first four weeks of implementation, there was a low uptake of utilizing the AHRQ decision aid tool by the registration or medical assistant/ nursing staff. The decision was made to move these tear-pad sheets into each of the 17 patient examination rooms and to provide a laminated copy for each room for the clinician to use with the decision aid. The one-page .pdf tool was also emailed to all practice PCPs as a reminder (Appendix G). This resource included current national, state and county lung cancer statistics; the seven question risk assessment tool;

suggested documentation requirements; and reimbursement coding for quick reference. Reminders to the HCP to document required components of SDM, use of a decision aid, and smoking cessation and abstinence counseling were included in the resource.

At the conclusion of the three-month implementation pilot (January 19, 2019 through April 19, 2019), change in provider lung cancer screening behaviors were measured compared to baseline (number who were eligible and referred for LDCT screening, number who were eligible and not screened, and number of eligible patients refusing LDCT referral). Due to the short duration of this pilot project we were not able to evaluate those who actually completed the LDCT once referred, nor the number of lung cancers detected upon LDCT referral.

The project was submitted to the University of North Carolina at Chapel Hill Institutional Review Board (IRB) for review and approval. The University of North Carolina at Chapel Hill IRB determined the submission did not constitute human subjects research as defined under federal regulations and did not require IRB approval.

Statistical Analysis

Descriptive statistics were used to analyze data regarding pre- and post-implementation patient demographics and variables related to LDCT screening. These tests included mean, median, minimum, maximum, frequencies and percentages. IBM SPSS Statistic software program was used to calculate the descriptive statistics for the study patients. To determine if the implementation of the risk assessment tool led to improved rates of LDCT referrals for Medicaid enrollees, the number who were eligible and referred for LDCT screening, number who were eligible and not screened, and number who were eligible but declined LDCT referral were compared before and after implementation using two proportion z-tests. The two proportion z-test was utilized to determine whether the proportion of those eligible and referred for screening, eligible and not screened, and eligible but declined referral are the same in the two groups. The sample size was greater than 30 with known mean and standard deviation. The z-test was also chosen because the number of eligible patients was almost equal with normal distribution and independent data points.

CHAPTER 3: RESULTS

Total Practice Medicaid Patients- Eligible, Did Not Participate: Demographics, Smoking History, Symptomatology and Smoking Cessation Counseling

To understand the population of Medicaid patients seen in this rural primary care practice, demographics related to age, gender, race, ethnicity, insurance and zip code were collected (Appendix H, Table 1). Additional information on pack-year smoking history, symptomatology and smoking cessation counseling was collected. Of the 184 Medicaid patients evaluated in the clinic during the study period, 150 of the total Medicaid practice sample were eligible but did not participate (were Medicaid enrollees- either single coverage or dual eligible; age 55-80 years; and positive smoking history).

Patient Sample: Demographics, Smoking History, Symptomatology Smoking Cessation Counseling

Thirty-four patients met eligibility criteria for lung cancer screening (were Medicaid enrollees; age 55-80; documented pack-years smoking history; and were asymptomatic) (Appendix I, Figure 2). The pre- and post-implementation cohorts of the patient sample (N=34) had similar demographics without any statistically significant differences found between groups (Appendix J, Table 2). There were also no significant differences between the pre- and post-implementation cohorts of patients related to pack-years smoking history and symptomatology (Appendix K, Table 3). Additionally, there were no significant differences in smoking cessation counseling, if needed, after implementation compared to before (Appendix L, Table 4).

Comparison of Total Medicaid Patient Sample and Eligible Patient Sample

The total practice Medicaid population (N=150) differed significantly from the eligible patients (N=34) in several areas (Appendix H, Table 1).

Age. The patients in the total Medicaid practice cohort were statistically significantly younger than the eligible patient cohort. The total Medicaid practice cohort had a mean (SD) patient age of 61.9 (4.87) years while the patient sample (N=34) were older with a mean (SD) age of 66.5 (5.25) years (p=0.00004).

Gender. There were no significant differences between the proportion of females (p=0.59) and males (p=0.59) in each cohort. The total Medicaid practice cohort had a higher proportion of females (n=85, 56.7%) compared to males (n=65, 43.3%). Similarly, the proportion of females (n=21, 61.8%) in the eligible patient group was higher than males (n=13, 38.2%).

Race. The total Medicaid population had a statistically significantly higher proportion of Black/ African Americans (n=81, 54.0%) compared to the eligible patient group of Black/ African Americans (n=7, 20.6%, p=0.00008). The total Medicaid practice population also had a statistically significantly lower proportion of White/ Caucasians (n=63, 42%) than the patient sample (n=27, 79.4%, p=0.00008).

Ethnicity. There were no significant differences in ethnicity between the total Medicaid practice population and the eligible patients. There were low proportions of Hispanic/ Latinos (n=5, 3.3%) in the total Medicaid practice population while there were none in the eligible patient group (p=0.28). There was a high proportion of the total Medicaid practice population identified as Not Hispanic/ Not Latino (n=142, 94.6%) as well as in the eligible patient group (n=34, 100%, p=0.17).

Insurance. The total Medicaid practice population had a statistically significantly higher proportion of patients with North Carolina Medicaid only (n=58, 38.7%) compared to the eligible patient group (n=5, 14.7%, p=0.01). The total Medicaid practice population had a statistically significantly lower proportion of patients with dual eligibility with North Carolina Medicaid and Medicare (n=92, 61.3%) compared to the eligible patients (n=29, 85.3%, p=0.01).

Zip code. There were no significant differences between zip codes of the two cohorts. The total Medicaid practice population had a similar proportion of patients from within the immediate Vance County area zip codes of 27536 and 27537 (n=108, 72%) compared to all other zip codes outside of Vance County. The proportion of eligible patients from within the immediate Vance County area zip codes of 27536 and 27537 was 67.6% (n=23) compared to zip codes outside of Vance County.

Pack-year smoking history and symptomatology. There was a high proportion of patients in the total Medicaid practice population who had no pack-year history documented (n=118, 78.7%). A significantly higher proportion of the eligible patients had a documented $\geq$30 pack-year smoking history (n=23, 67.6%) compared to the total Medicaid practice population (n=28, 18.7%, p=0.00001). A significantly higher proportion of the eligible patients had a documented <30 pack-year smoking history (n=11, 32.6%) compared to the total Medicaid population (n=4, 2.7%, p=0.00001).

Of the total Medicaid practice population with a documented pack-year history (n=32), all were symptomatic (100%) and were determined ineligible for LDCT lung cancer screening. None of the 34 patients eligible for LDCT lung cancer screening were symptomatic.

Smoking cessation counseling. There were no significant differences between the proportion of patients receiving smoking cessation and abstinence counseling, if needed, between the cohorts. Overall, a slightly higher proportion of the eligible patients received smoking cessation counseling, if needed, (n=17, 50%) compared to the total Medicaid practice population (n=60, 40%, p=0.285).

Primary Outcome Measure: Referred for LDCT Screening

To measure improvement in LDCT screening referrals of the eligible patients (N=34), referral was determined as either "yes" or "no". There was not a statistically significant improvement in referrals following implementation (p = 0.23). There were more patients referred for LDCT screening during the post-implementation period (n=3, 19%) compared to the pre-implementation period (n=1, 6%) but this did not reach statistical significance (Appendix M, Table 5).

Secondary Outcome Measure: Not Referred for LDCT Screening

Patients who met all criteria for LDCT screening referral yet were not referred were determined as either "yes" or "no". There was no statistically significant change in the percentage of patients who met all eligibility criteria for LDCT screening but were not referred between and pre-implementation (n=11, 61%) and post-implementation (n=8, 50%) groups (p=0.51) (Appendix M, Table 5).

Secondary Outcome Measure: Referred and Declined LDCT Screening

There were no patients in either of the pre- or post-implementation cohorts who were referred by the PCP but declined to undergo LDCT screening (Appendix M, Table 5).

CHAPTER 4: DISCUSSION

The goal of this DNP quality improvement project was to improve lung cancer screening in eligible Medicaid recipients in a rural primary care practice. The process to improve screening included incorporating a lung cancer risk assessment tool into the practice EHR to assist the PCP to appropriately identify eligible patients for LDCT screening and to increase appropriate LDCT screening referrals. Thirty-four patients met the USPSTF lung cancer screening eligibility criteria (ages 55-80, documented pack-year smoking history and asymptomatic) from the Medicaid practice population (N=184) seen during the study period. Data was gathered for three months before and after implementation of the lung cancer risk assessment tool in order to evaluate the impact on provider lung cancer screening behavior. Our project found no significant improvement in the primary outcome of LDCT screening referrals. Post-implementation screening rates in this study increased to 19%; however, this was not statistically significant.

National LDCT lung cancer screening rates are low at 1.9% in the general population (Pham et al., 2018). Pre-implementation screening rates in this study were higher at 5.6%, and were consistent with other research findings of LDCT screening rates of 5.8% in a high-risk smoker population in California in the National Health Interview Surveys (Li, Chung, Wei & Luft, 2018). There is currently no data published on the estimated or actual numbers of lung cancer screenings in the North Carolina general population or in the North Carolina Medicaid population for comparison.

A high proportion of patients in our total Medicaid practice population had no pack-year smoking history documented (n=118, 78.7%). Recommending LDCT screening in a targeted, high-risk population is designed to decrease the burden of screening (including false-positive follow-up and screening anxiety) (Goulart & Ramsey, 2013). Incomplete documentation of smoking history to include accurate pack-year history can negatively impact the numbers of patients who actually meet USPSTF lung cancer screening criteria. Smoking history documentation remains an area for improvement at this practice site for continued improvement in LDCT screening referral rates.

Determining screening eligibility can remain confusing for the PCP even when the pack-year smoking history is known. Research has shown that selection of patients for LDCT screening using an individualized risk assessment tool is superior (greater sensitivity and specificity) to the current eligibility criteria based on patient age and pack-year smoking history alone (O'Dowd & Baldwin, 2017). In this project there was a non-statistically significant improvement in the proportion of patients who met all criteria for LDCT referral in the post-implementation cohort (n=8, 50%) but were not referred compared to the pre-implementation cohort (n=11, 61.1%). The three patients who were referred for LDCT screening during the post-implementation period were also seen in the pre-implementation period but were not referred at that time despite knowing the age, pack-year smoking history and symptomatology. Review of the EHR revealed no documented reason why they were not initially considered or evaluated for LDCT referral as they did meet USPSTF eligibility criteria at that time. It is plausible that the education efforts in this project, combined with the lung cancer risk assessment screening tool, were effective in prompting the PCP to evaluate these patients on their subsequent visits for eligibility for LDCT screening referral. Utilizing a LDCT screening tool may be challenging during a primary care visit but is an important aspect of expanding clinician knowledge and changing clinician behavior (Li et al., 2018).

Importantly, all patients referred for LDCT during both the pre-implementation period (n=1) and the post-implementation period (n=3) had documentation of all required elements for payor coverage. Additionally, all patients who were referred for LDCT during both the pre- and post- implementation periods (n=4) had documentation of smoking cessation and abstinence counseling.

Recent debate has questioned if the current USPSTF lung cancer screening guidelines are too stringent to apply to African American adult smokers, suggesting that the guidelines may be too conservative for this specific population citing racial differences in smoking patterns (Aldrich et al., 2019). Our study found African Americans represented only 21% (n=7) of eligible patients using current USPSTF lung cancer screening eligibility criteria. Suggestions for modification of the eligibility criteria for this population include decreasing the current 30 pack-year eligibility to 20 pack-years, as well as decreasing the minimum age to begin consideration for LDCT lung cancer screening from the current 55 years to 50 years (Aldrich et al., 2019). Our study quantified pack-year history as only $\geq$30 or $<$30 pack-years. However, proactively looking at more descriptive pack-year smoking quantities could help to inform future screening criteria for specific populations. Although decreasing the USPSTF recommendations in the adult African American smoker population may increase the percentage eligible for screening, these suggestions are not recommended in current guidelines or in clinical practice as it would likely result in failure of payment by CMS and private insurances.

Smoking cessation and abstinence counseling remains a cornerstone of a successful LDCT lung cancer screening program. All eligible patients (N=34) were current smokers with pack-year history documented. Despite this information, there was no change in the proportion of patients with documented smoking cessation counseling during the pre- and post-implementation periods. There continues to be a need for PCP and staff education and clarification around the issue of smoking cessation and abstinence counseling as well as documentation requirements.

CHAPTER 5: LIMITATIONS AND PRACTICE IMPLICATIONS

Limitations of this study include the small patient sample (N=34), which may contribute to the lack of statistically significant findings and limits the generalizability to a larger population.

Additional limitations include the lack of significant process changes during the project. The low uptake of utilizing the AHRQ decision aid tool by the registration or medical assistant/ nursing staff was identified following the first month of implementation. Only a small change was made in the ownership of distribution of the decision aid to the PCP. During a practice change project of this type, one would expect implementing changing the intervention utilizing PDSA cycles to improve smoking history documentation and uptake of the screening tool. The Plan-Do-Study-Act (PDSA) cycle is a commonly used improvement process in health care settings that uses small tests of change to optimize a process (Coury et al., 2017). However, as a DNP student with limited access to the clinic, staffing and data at the study site, these results may have been different than if employed full-time at the site with daily presence to enact changes to improve smoking history documentation and uptake of the screening tool.

Due to the short duration of the pilot project, the outcomes of the LDCTs ordered were not evaluated, which would be monitored in a real life clinical setting.

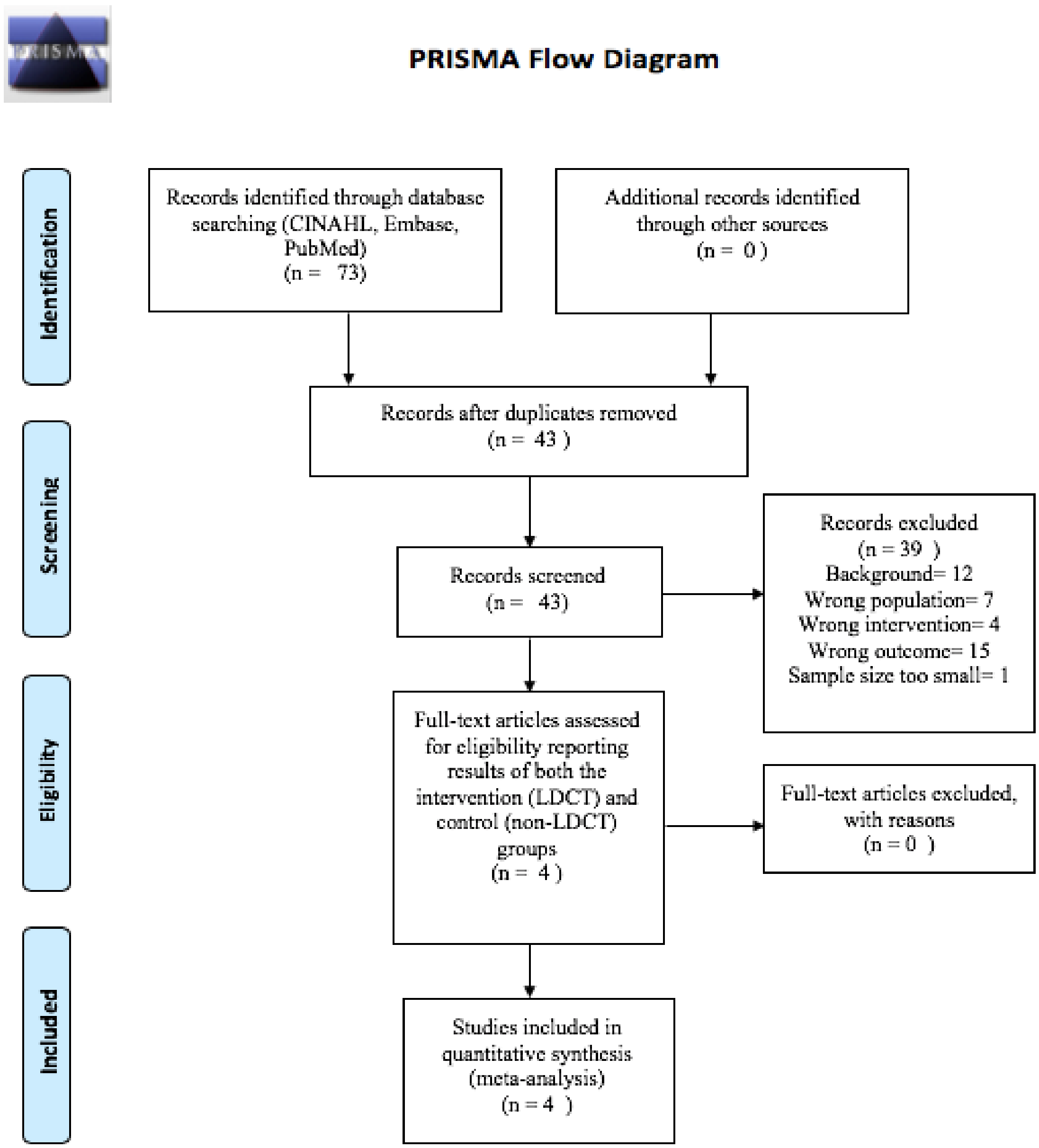
Recommendations for future work include continuing to review and improve upon the process of gathering accurate USPSTF lung cancer screening patient eligibility criteria of pack-years smoking history and documenting this in the EHR. This work will allow for automation of appropriate patient identification for screening from the EHR database. Specific questions to be investigated in future analyses include:

- How does the documentation of pack-year smoking history improve LDCT referral rates in a high-risk North Carolina Medicaid population? Comparisons from this site could then be compared to other primary care practice sites within North Carolina.
- What is the impact of this project on the LDCT screening referral rates in the non-Medicaid patients within the practice? This information could inform about PCP learnings and application of LDCT screening and referral within the general practice.

CHAPTER 6: CONCLUSIONS

LDCT screening guidelines have not been widely implemented into national evidence-based clinical practice as evidenced by a low national lung cancer screening rates. The PCP most often represents the initial point of coordination of preventative care and is an important link between the high-risk lung cancer patient and the LDCT screening center. The PCP is well positioned to assist the patient with decision-making for lung cancer screening interventions. However, the PCP needs system changes to facilitate this process. While this single site quality improvement project did not show improvement in LDCT screening referral rates, it does provide data on current LDCT referral rates in a high-risk North Carolina Medicaid population which is currently not in the published health care literature.

APPENDIX A: PRISMA FLOW DIAGRAM



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *Meta-Analyses*: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

APPENDIX B: LITERATURE REVIEW

Summary of findings:

How effective is low dose chest tomography (LDCT) screening for lung cancer in reducing morbidity and mortality in a high risk population?

Population: Adults men and women (over 18 years) at high riskfor lung cancer

Setting: Worldwide

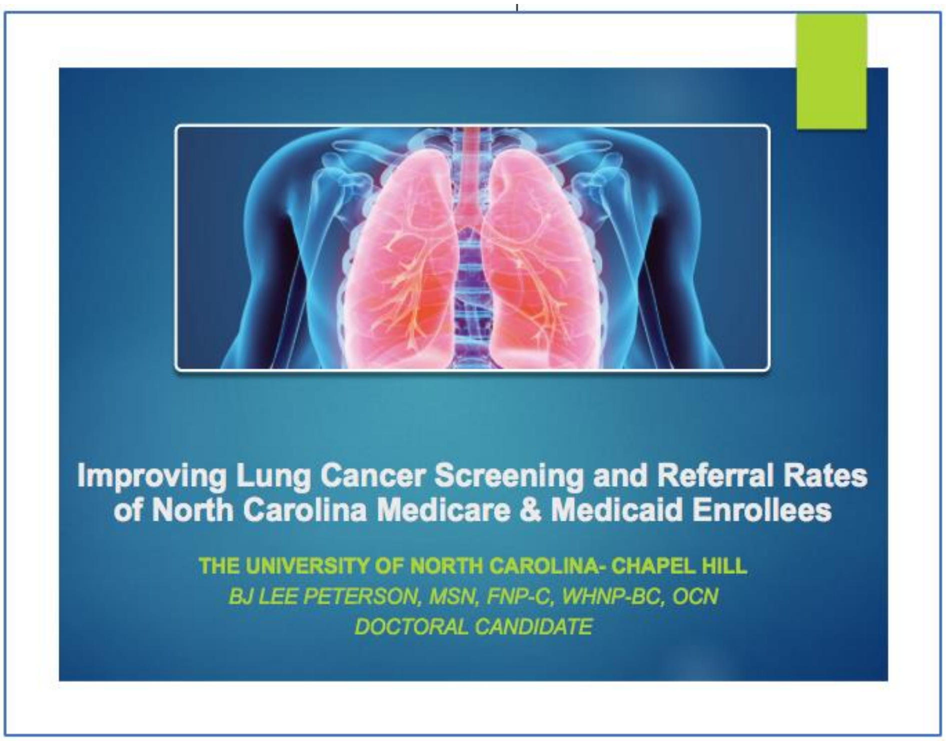
Intervention: Low dose chest tomography (LDCT) lung cancer screening

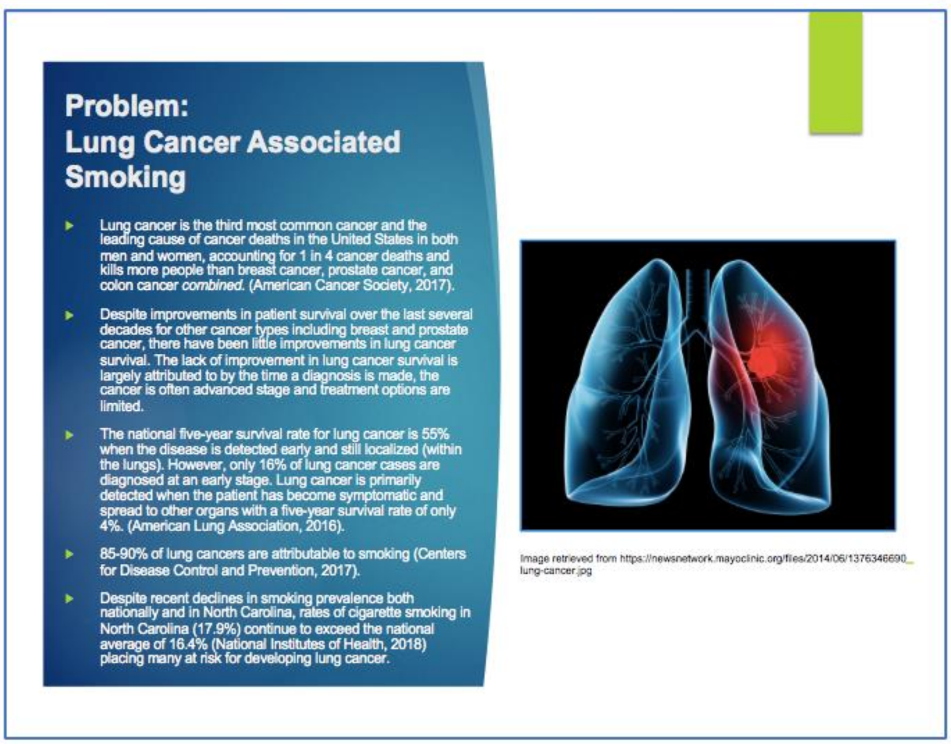
Comparison: No LDCT screening (CXR or usual care)

Publication/ Year	Country/ Sites	Subject (N)/ Median Follow-Up	Population	Smoking Risk/ Mean Smoking History	Screening comparator	Abnormal finding follow-up	Results: Intervention vs. Control	Comments	Overall quality of evidence
NLST, 2011 Aberle (National Lung Screening Trial Research Team) et al *Reduced lung-cancer mortality with low-dose computed tomographic screening*	United States Multicenter (10LSS centers and 23 ACRIN centers)	53,454 (26,722 vs 26,732) Median Follow-Up: 6.5 years	Ages 55-74	Current of former (quit ≤15 years ago) with ≥30 pack year smoking history Mean Smoking History: 56 pack-years	CT vs CXR: CT:Low-dose (1.5mSv), multidetector, >4 channels CXR:1 view, PA with deep inspiration	Radiologist provided results and recommendations to subject's community provider	**Lung cancer mortality**: 247 per 100,000 person-years (356) vs 309 per 100,000 person-years (443); RRR 20% (95% CI, 6.8-27%) **All-cause mortality**: (1877 vs 1998); RRR 6.7% (95% CI, 1.2-13.6%, p=0.02) **Stage at diagnosis**: 51.8% (329 of 635) vs 32.7% (90 of 275) Stage 1A; 11.2% (71 of 635) vs. 14.9% (41 of 275) Stage 1B	Sponsor: NCI Good external validity; No loss to follow-up	Good
DANTE, 2009 Infante et al. *A randomized study of lung cancer screening with spiral computed tomography: three-year results from the DANTE trial.*	Italy (3 hospitals from same network)	2472 (1276 vs 1196) Median Follow-Up: 2.9 Years	Ages 60-74	Asymptomatic men curren tor former smoker with >20 pack year smoking history Mean Smoking History: 47 pack-years	CT vs annual clinical review	Evaluated within study per established study protocol	**Lung cancer mortality**: 558 per 100,000 person-years- 20 (1.6%) vs 597 per 100,000 person-years- 20 (1.7%) (RR 0.83 [95% CI, 0.45-1.54]) **All-cause mortality**: 46 (3.6%) vs 45 (3.8%) ; RR 0.85 [95% CI, 0.56- 1.27]) **Stage at diagnosis**: Stage I-33 (2.6%) vs 12 (1.0%); Stage II-4 (0.3%) vs 2 (0.2%); Stage III- 13 (1.1%) vs 7 (0.6%); Stage IV- 11 (0.9%) vs 14 (1.2%)	Sponsor: Italian Association for the Fight Against Cancer; External validity- Fair (only men); Less follow-up in controls (31.5mos vs 35.7 mos in LDCT)	Fair
DLCST, 2012 Saghir et al *The Danish Randomized Lung Cancer CT Screening Trial- overall design and results of the prevelance round*	Denmark single site	4104 (2052 vs 2052) Median Follow-Up: 4.8 Years	Ages 50-70	Healthy men and women. Current and former smokers (<10 years and > 4 weeks since smoking cessation) with ≥20 pack year smoking history Mean Smoking History: 36 pack-years	LDCT vs usual care	CT screen cohort- single center affiliated with study Control cohort- mostly same specialists	**Lung cancer mortality**: 154 per 100,000 person-years- 15 (0.7%)vs 112 per 100,000 person-years- 11 (0.5%) (RR 1.37 [95% CI, 0.63-2.97]) **All-cause mortality**: 61 (3.0%) vs 42 (2.1%) p=0.059 **Stage at diagnosis**: 54 vs 10 Stage I or II (p,0.001); 44 vs 8 Stage III; 21 vs 16 Stage IV	Sponsor: Danish Ministry of Interior and Health; External validity- Good; Study reports less complete follow-up among controls	Fair
MILD, 2012 Pastorino et al *Annual or biennial CT screening versus observation in heavy smokers: 5-year results of the MILD trial*	Milan Single institution	4099 (1190 vs 1186 vs 1723) Median Follow-Up: 3.8 Years	Ages ≥49	Smokers with a ≥20 pack year smoking history or quit ≤10 years ago Mean Smoking History: 38-39 pack-years	LDCT (annual vs biennial) vs usual car	nodules >250mm3; volumetric follow-up of intermediate nodules	**Lung cancer mortality**: (HR 1.64 [95% CI, 0.67- 4.01]); **All-cause mortality**: (RR 1.40 [95% CI, 0.82- 2.38]) control; (RR 1.80 [95% CI, 1.03-3.13]) annual; (RR 1.17 [95% CI, 0.63- 2.17]) biennial; **Stage at diagnosis**: Stage IA: 59% (annual) vs. 55% (biennial) vs. NR (control); Stage IV: 17% (annual) vs. 15% (biannial) vs. NR (control)	Ministry of Health; External validity- Good; Significant difference in follow-up (44.9mos controls vs 56mos in LDCT)	Poor

LSS- Lung Screening Study group; ACRIN- American College of Radiology Imaging Network; CT- Chest Tomography; CXR- Chest Radiograph; PA- Posterioranterior; RRR- Relative Risk Reducation; T0- Baseline screening, completed annually; T1- Year one screening, completed annually; T2- Year two screening, final screening; NCI- National Cancer Institute; LDCT- Low Dose Chest Tomography; PET- Positron Emission Tomography

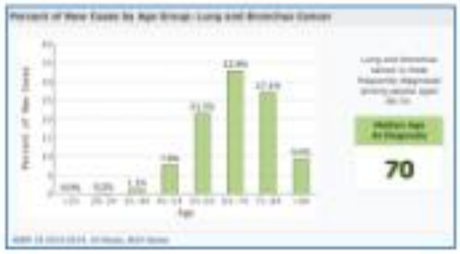
APPENDIX C: IMPLEMENTATION SITE TRAINING POWERPOINT PRESENTATION





New Lung Cancer Cases in the United States by Age

- Lung cancer mainly occurs in older people. Most people diagnosed with lung cancer are 65 or older, while few are diagnosed younger than 45.
- The average age at the time of diagnosis is about 70.



North Carolina Cancer Prevention and Control Branch/N.C. Comprehensive Cancer Control Program (2017). *Reducing the burden of cancer in North Carolina. A data and resource guide for communities to fight cancer* [Online image]. Retrieved from http://publichealth.nc.gov/chronicdiseaseandinjury/cancerpreventionandcontrol/docs/ReducingtheBurdenofCancerResourceGuide.pdf

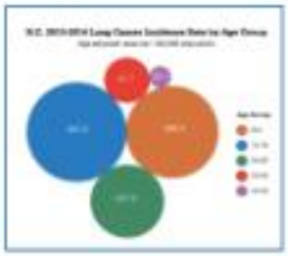
The Burden of Lung Cancer in the United States and North Carolina and Its Consequences

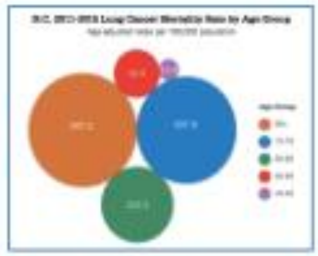
- In 2017, more than 222,500 Americans were diagnosed with lung cancer and about 155,870 died of the disease, making it the leading cause of cancer deaths in the nation (National Cancer Institute, 2017).
- The burden of lung cancer in North Carolina is, on average, higher than that of the United States. North Carolina's incidence and mortality rates exceed that of national rates for lung.
- It is estimated that 8,888 North Carolinians will be diagnosed with lung cancer and 6,168 people will die from lung cancer in 2017. Lung cancer was the leading cause of cancer deaths (28.3%) in North Carolina in 2015 (North Carolina Cancer Prevention and Control Branch/N.C. Comprehensive Cancer Control Program, 2017).

North Carolina Cancer Prevention and Control Branch/N.C. Comprehensive Cancer Control Program (2017). [Online image]. Retrieved from http://publichealth.nc.gov/chronicdiseaseandinjury/cancerpreventionandcontrol/docs/ReducingtheBurdenofCancerResourceGuide.pdf

North Carolina Lung Cancer Incidence and Mortality Rates by Age Group

- Individuals between the ages of 70 and 79 in North Carolina have the highest rates for lung cancer.
- Individuals 60 years old and above have a combined incidence rate that is over nine times higher than that of individuals younger than 60 years old.
- Individuals 80 years old and above have the highest lung cancer mortality rate.

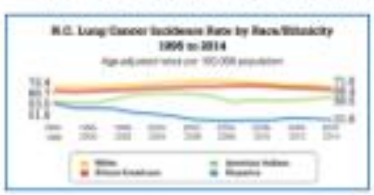




North Carolina Cancer Prevention and Control Branch/N.C. Comprehensive Cancer Control Program (2017). *Reducing the burden of cancer in North Carolina: A data and resource guide for communities to fight cancer* [Online image]. Retrieved from http://publichealth.nc.gov/chronicdiseaseandinjury/cancerpreventionandcontrol/docs/ReducingtheBurdenofCancerResourceGuide.pdf

North Carolina Lung Cancer Incidence by Race

- Lung cancer is one of the few cancers in which African Americans fare slightly better than Whites in incidence and mortality rates on a statewide level
- African Americans are still more likely to be diagnosed at the distant stage (cancer has spread to distant parts of the body) of lung cancer (53% of cases). Hispanics across the state fare better than any other measurable racial/ethnic group in lung cancer incidence and mortality. The lung cancer incidence rate for American Indians has risen since 1996 more than any other measurable racial/ ethnic group in the state (North Carolina Cancer Prevention and Control Branch/N.C. Comprehensive Cancer Control Program, 2017).



North Carolina Cancer Prevention and Control Branch/N.C. Comprehensive Cancer Control Program (2017). *Reducing the burden of cancer in North Carolina: A data and resource guide for communities to fight cancer* [Online images]. Retrieved from http://publichealth.nc.gov/chronicdiseaseandinjury/cancerpreventionandcontrol/docs/ReducingtheBurdenofCancerResourceGuide.pdf

Risk Factors for Lung Cancer: Smoking

- Nearly 9 out of 10 lung cancers are caused by smoking cigarettes with smokers having a greater risk for lung cancer today than they did in 1964, even though they smoke fewer cigarettes. One reason may be changes in how cigarettes are made and what chemicals they contain (U.S. Department of Health and Human Services, 2015).
- Although the decline in overall cigarette smoking prevalence during 2005–2013 from 20.9% to 17.8% is encouraging, approximately 42.1 million adults still smoke cigarettes (Jamal, A., Agaku, I., O'Connor, E., King B, Kenemer, J., & Neff L., 2014).
- In 2014, approximately 40% of adult Americans were current or former smokers (Jamal, A., Agaku, I., O'Connor, E., King B, Kenemer, J., & Neff L., 2014).

Image retrieved from http://www.cdc.gov/tobacco/data_statistics/fact_sheets/ adult_data/cig_smoking/

Social Determinants, Disparities, Inequities and Care Gaps: Smoking Related Lung Cancer in North Carolina Medicaid Enrollees

- North Carolina Medicaid smoking rates (2016) are staggering placing these enrollees at high risk for lung cancer (State Center for Health Statistics, North Carolina Department of Public Health, 2016).
  - 43.3% of non-institutionalized adults aged 18-64 years reported current smoking
  - 32.2% with no health insurance reported smoking
  - 16.2% with other health insurance
- Outcome disparities among low-income populations demonstrate they are at higher risk for poor treatment outcomes (North Carolina Department of Health and Human Services, 2017).
- Patients with Medicaid or no insurance consistently have worse outcomes than other patients with lung cancer (Mendes, E., 2013).
  - Higher risks of death than privately insured patients
  - African-Americans and Hispanics—groups that are disproportionately represented in Medicaid programs—have higher lung cancer incidence and higher lung cancer mortality rates when compared with non-Hispanic whites and those with higher socioeconomic status
  - Lung cancer patients in rural areas are disadvantage relative to their urban peers
  - Medicaid beneficiaries are often in poor health before their lung cancer diagnosis—making their treatment much more complex
  - Higher co-morbidity rates: more than a third are obese; approximately 20 percent are being treated for depression or high blood pressure; and 15 percent have diabetes

North Carolina County Rankings

- North Carolina County Rankings: Lung Cancer Incidence Rate (2010- 2014), Lung Cancer Mortality Rate (2011-2015), Distant Stage Diagnosis (2010- 2014), Current Smoker (2012), and Insurance Status (Uninsured at Diagnosis 2010-2014)

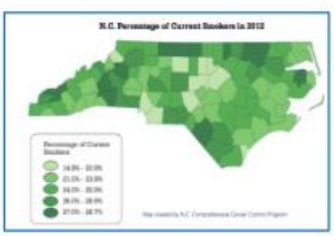
  Yellow: Four Categories in Top Quintile- McDowell

  Yellow: Three Categories in Top Quintile Caldwell, Columbus, Gaston, Harnett, Hyde, Person, Scotland, Stoke Vance

North Carolina Cancer Prevention and Control Branch/N.C. Comprehensive Cancer Control Program (2017). *Reducing the burden of cancer in North Carolina: A data and resource guide for communities to fight cancer.* Retrieved from: https://publichealth.nc.gov/chronicdiseaseandinjury/cancerpreventionandcontrol/docs/ReducingtheBurdenofCancerResourceGuide.pdf

Smoking Related Lung Cancer in North Carolina

- Rates of cigarette smoking in North Carolina continue to exceed the national average of (17.9% vs. 16.4%) placing many North Carolinians at risk for developing lung cancer (National Institutes of Health, 2018).



N.C. Counties where the Percentage of Current Smokers Exceeding 26%

County	Percentage of Current Smokers	County	Percentage of Current Smokers
North Carolina	**21%**	Edgecombe	27%
Vance	29%	Graham	27%
Robeson	29%	Randolph	27%
McDowell	28%	Columbus	27%
Caswell	28%	Wilkes	27%
Rockingham	28%	Mitchell	26%
Northampton	28%	Anson	26%
Caldwell	28%	Bladen	26%
Tyrrell	27%	Gaston	26%
Stokes	27%	Rowan	26%
Rutherford	27%	Cleveland	26%
Halifax	27%	Richmond	26%
Swain	27%	Burke	26%
Warren	27%	Bertie	26%

North Carolina Cancer Prevention and Control Branch/N.C. Comprehensive Cancer Control Program (2017). *Reducing the burden of cancer in North Carolina: A data and resource guide for communities to fight cancer* [Online image]. Retrieved from http://publichealth.nc.gov/chronicdiseaseandinjury/cancerpreventionandcontrol/docs/ReducingtheBurdenofCancerResourceGuide.pdf

Highest Percent of People Enrolled in Medicaid as of January 2017

Highest Percent of People Enrolled in Medicaid as of January 2017: 32%- 40%
Number of People Enrolled in Medicaid as of January 2017:
10,000- 19,999- Edgecombe, Halifax, Richmond, Scotland, Vance
20,000- 49,999- Robeson

Toledo, L. (2017). *Understanding Medicaid and its impact in North Carolina: A Chart Book.* North Carolina Justice Center, Budget and Tax Center.

North Carolina Medicaid Coverage for LDCT

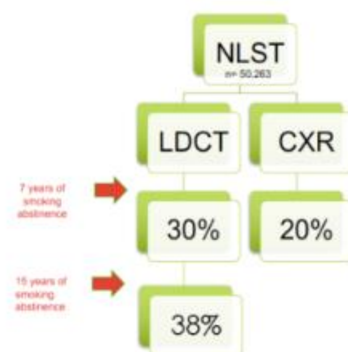
- **Currently all sectors of high risk populations have access to lung cancer screening by LDCT:**
  - Private insurers are required to cover any screening given an "A" or "B" recommendation by the USPSTF
    - No deductibles or co-payments for initial screening
    - May have costs to pay if requires diagnostic evaluation of abnormal on screen
  - CMS mandated coverage (2015)- Medicare coverage
- **NC Medicaid Population: (Must meet all criteria)** (EviCore, 2018).
  - Asymptomatic
  - 50- 80 years
  - Current smoker with > 30 pack years or < 15 year smoking cessation history
  - Patient has not received a low-dose CT lung screening in less than 12 months; and
  - Patient has NO health problems that substantially limit life expectancy or the ability or willingness to have curative lung surgery*
- **Recommendations:**
  - USPSTF Grade B (moderate net benefit)
  - Annual LDCT until no smoking > 15 years
- NC Medicaid is currently meeting the USPSTF recommendations for lung cancer screening/preventive services. NC Medicaid covers low dose CT using CPT 71250. **A prior authorization through EviCore, NC Medicaid's high tech imaging vendor, is required.** EviCore's phone # 1-800-575-4517 for prior approval request of CPT 71250. (***Not** the usual G0297- LDCT for lung cancer screening code)
- For those without insurance coverage, the average cost for a low-dose chest tomography scan for lung cancer in North Carolina ranges from $250-500 (The Lung Cancer Initiative of North Carolina, 2018).

Evidence-Based Strategies/ Interventions Outcomes & Evaluation: Lung Cancer Screening

- **Efficacy:**
  - The NLST: The National Lung Screening Trial (2011) randomized 53,454 high-risk individuals aged 55 to 74 years to three annual screenings with low dose chest tomography (LDCT) or standard chest x-rays (CXR) and followed them for a median of 6.5 years (Aberle, D., et al., 2011).
  - LDCT vs. CXR and usual care, provided (high risk population):
    - 20% reduction in lung cancer mortality
    - 6.7% reduction in all cause mortality
    - 95% CI, 6.8- 26.7; P=0.004
- **Number Needed To Screen (NNTS) to prevent 1 cancer death with LDCT= 320**
  - Mammogram= 900-1900
  - Colonoscopy= 500

Evidence-Based Strategies/ Interventions Outcomes & Evaluation: LCS & Smoking Abstinence

- **Important Impact of Smoking Abstinence in the NLST** (Tanner, N., et al., 2016)
  - Current smokers had an increased lung cancer specific (hazard ratio [HR], 2.14-2.29) and all-cause mortality (HR, 1.79-1.85) compared with former smokers irrespective of screening arm
  - Former smokers in the control arm abstinent for 7 years had a 20% mortality reduction comparable with the benefit reported with LDCT screening in the NLST
  - The maximum benefit was seen with the combination of smoking abstinence at 15 years and LDCT screening, which resulted in a 38% reduction in lung cancer-specific mortality (HR, 0.62; 95% confidence interval, 0.51-0.76)



Potential Harms of LDCT Screening

Complication of diagnostic procedure: (Bach, P. et al., 2012)

In NLST:

- Low frequency of major complications occurring during a diagnostic evaluation of a detected finding:
  - LDCT: 33 per 10,000 individuals screened
  - CXR: 10 per 10,000 individuals screened
- Frequency of death occurring within 2 months of a diagnostic evaluation of a detected finding (any cause):
  - LDCT: 8 per 10,000 individuals screened
  - CXR: 10 per 10,000 individuals screened
- Radiation Exposure:
  - Radiation dose is 1.5mSv per LDCT Screening
  - Average of approximately 8mSv per patient over 3 years (includes both screening and diagnostic tests)
  - 1 cancer death may be caused by radiation from imaging per 2,500 persons screened

Type	Effective Dose	Natural Background	Risk
Chest Xray	0.1 mSv	10 days	Minimal
Mammogram	0.4 mSv	7 weeks	Very Low
Low Dose Chest CT	1.5 mSv	months	Very Low
Spine CT	6 mSv	2 years	Low
Diagnostic Chest CT	7 mSv	2 years	Low
Abdomen/ Pelvis CT with/ without contrast material	20 mSv	7 years	Moderate

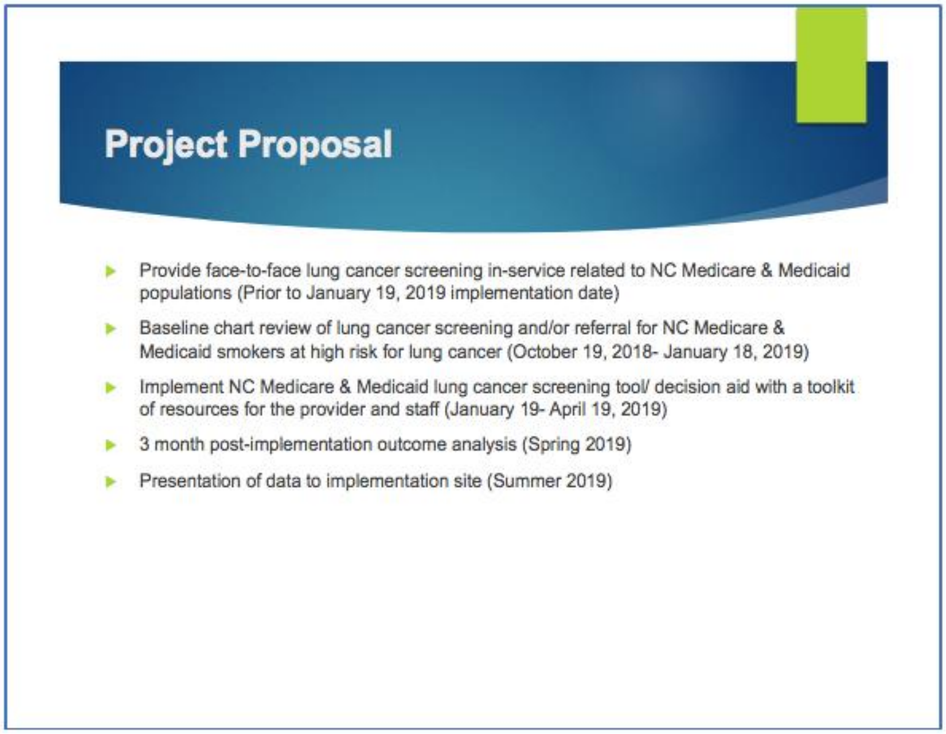
Bach, P. et al., (2012). Benefits and harms of CT screening for lung cancer: a systematic review [Online image]. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3709596/pdf/nihms465275.pdf

Patients are not being screened and/ or referred for LCS

- 2010 National Health Interview Survey found that only 3.3% of high risk smokers had been screened by LDCT the previous year (Jemal & Fedewa, 2017).
  - 2015 National Health Interview Survey found that only 3.9% of high risk smokers were screened by LDCT
  - In 2015, only 262,700 of the eligible 6.8 million current and former smokers were screened for lung cancer
- In 2016, only 1.9% of 7.6 million eligible smokers were screened by LDCT for lung cancer (Pham et al, 2018).
  - Screening rates varied by region, from 3.5% in the Northeast to 1% in the West.
  - The majority of eligible smokers were in the South, yet only 1.6% underwent LDCT screening
  - The South had the most accredited screening sites (663 of 1,796)

Jemal, A. and Fedewa, S. (2017). Lung cancer screening with low-dose chest tomography in the United States- 2010 to 2015. *Journal of the American Medical Association Oncology*, 3(9); 1278-1281.

Pham, D., Bhandari, S.,Oechsli, M., Pinkston, C., Kloecker, G. (2018). Lung cancer screening rates: Data from the lung cancer screening registry. Journal of Clinical Oncology, 36(15; suppl). Retrieved from http://abstracts.asco.org/214/AbstView_214_221571.html on July 30, 2018.


Project Proposal
Provide face-to-face lung cancer screening in-service related to NC Medicare & Medicaid populations (Prior to January 19, 2019 implementation date)
Baseline chart review of lung cancer screening and/or referral for NC Medicare & Medicaid smokers at high risk for lung cancer (October 19, 2018- January 18, 2019)
Implement NC Medicare & Medicaid lung cancer screening tool/ decision aid with a toolkit of resources for the provider and staff (January 19- April 19, 2019)
3 month post-implementation outcome analysis (Spring 2019)
Presentation of data to implementation site (Summer 2019)

APPENDIX D: ELIGIBILITY DETERMINATION FOR LDCT SCREENING REFERRAL

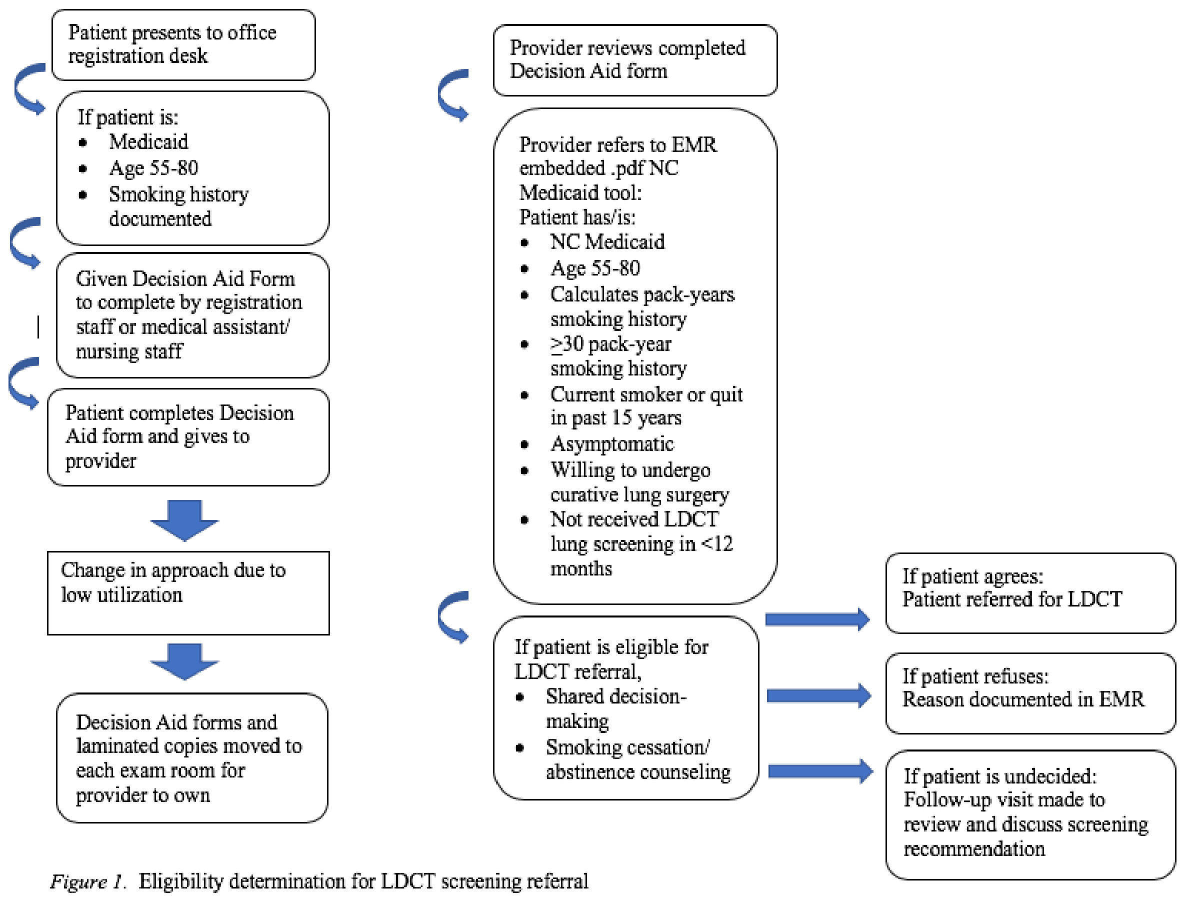


Figure 1. Eligibility determination for LDCT screening referral

APPENDIX E: AHQR "IS LUNG CANCER SCREENING RIGHT FOR ME. A DECISIONMAKING TOOL FOR YOU AND YOUR HEALTH CARE PROFESSIONAL

Is lung cancer screening right for me?

A Decisionmaking Tool for You and Your Health Care Professional

If you have smoked for many years, you may want to think about lung cancer screening (testing) with low-dose computed tomography (LDCT). Before making a decision, you should think about the possible benefits and harms of lung cancer screening.

What are the possible benefits and harms of lung cancer screening with LDCT?

BENEFIT: Greater chance of not dying from lung cancer

- If 1,000 people are not screened for lung cancer with LDCT, **21 will die from lung cancer.**
- If 1,000 people are screened once a year with LDCT for 3 years, **18 will die from lung cancer.**
- This means that with LDCT screening, **3 fewer people will die from lung cancer.**

BENEFIT: Greater chance of not dying from any cause (not just lung cancer)

- If 1,000 people are not screened for lung cancer with LDCT, **75 will die from any cause.**
- If 1,000 people are screened once a year with LDCT for 3 years, **70 will die from any cause.**
- This means that with LDCT screening, **5 fewer people will die from any cause.**

HARM: False alarms and unneeded additional testing

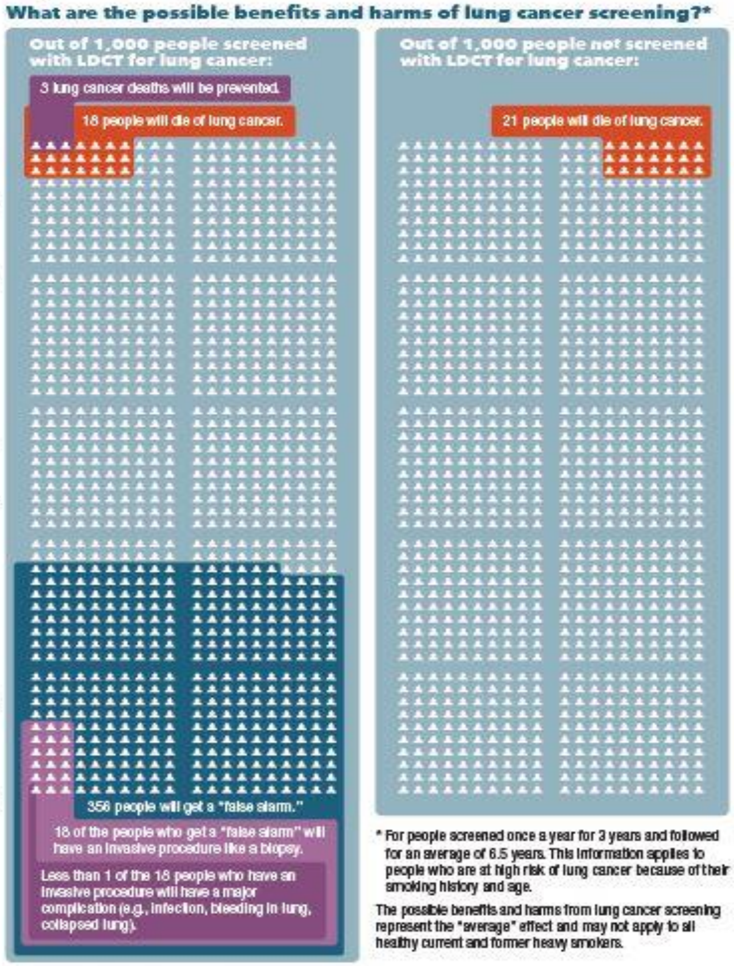
A false alarm happens when a person has a positive screening test but does not actually have lung cancer.

- If 1,000 people are screened every year for 3 years, about **356 will have a false alarm.**
- Of these 356 people with a false alarm, **18 will have an invasive procedure** such as a biopsy (a tiny piece of lung tissue is removed to test for cancer).
- Of these 18 people, **less than 1 will have a major complication** as a result of the procedure, such as bleeding in the lung, a collapsed lung, or an infection.

If you have a positive screening test, but your followup imaging tests and biopsy do not show cancer, you could still get lung cancer in the future. So it is important for you and your health care professional to discuss lung cancer screening every year.

AHRQ
Agency for Healthcare Research and Quality
Advancing Excellence in Health Care • www.ahrq.gov

What are the possible benefits and harms of lung cancer screening?*



* For people screened once a year for 3 years and followed for an average of 6.5 years. This information applies to people who are at high risk of lung cancer because of their smoking history and age.

The possible benefits and harms from lung cancer screening represent the "average" effect and may not apply to all healthy current and former heavy smokers.

HARM: Radiation Exposure

This includes radiation from screening plus radiation from additional testing. High doses (amounts) of radiation increase a person's chance of developing cancer.

HARM: Overdiagnosis

Screening may find lung cancer that would not have harmed the person in his or her lifetime.

Finding other things that are not lung cancer:

For example, screening can find heart disease or thickened tissue in the lungs from scarring. Researchers do not know the possible benefits or harms of finding other things about your health through lung cancer screening.

WHAT ELSE SHOULD YOU THINK ABOUT WHEN DECIDING ABOUT LUNG CANCER SCREENING?

» Lung cancer screening should be done every year until you no longer need to be screened.

» Lung cancer screening may not be right for you if you develop other major health problems.

» If you are not willing to have lung surgery, lung cancer screening may not be right for you.

» Lung cancer screening is not a substitute for quitting smoking.

INSURANCE COVERAGE

» Private insurance plans cover lung cancer screening for people age 55 through 80 with no out-of-pocket costs.

» Medicare covers lung cancer screening with no out-of-pocket costs for people up to age 77 years who meet other criteria.

» You and your insurance company will be responsible for the costs of additional tests and treatment after the initial screening test.

What is important to you when deciding?	Favors Screening				Favors No Screening
How important is:	Very Important				Not Important
Finding lung cancer early when it may be more easily treated?	◯	◯	◯	◯	◯
How concerned are you about:	Not Concerned				Very Concerned
Having a false alarm?	◯	◯	◯	◯	◯
Having other tests if you have a positive screening test?	◯	◯	◯	◯	◯
Being exposed to radiation from lung cancer screening?	◯	◯	◯	◯	◯
Being treated for lung cancer that never would have harmed you?	◯	◯	◯	◯	◯
Being harmed by the treatments you receive for lung cancer?	◯	◯	◯	◯	◯

WHAT OTHER QUESTIONS DO YOU HAVE?

____

____

____

____

____

____

WHAT IS YOUR DECISION ABOUT LUNG CANCER SCREENING?

◯ Screening is right for me. *(Ask your health care professional for the screening center information.)*

◯ Screening is not right for me.

◯ I am unsure about screening.

BENEFITS OF QUITTING SMOKING

» Lower risk for other types of cancer.

» Lower risk for heart disease, stroke, and narrowing of the blood vessels outside your heart.

» Fewer problems with breathing, such as coughing, wheezing, or shortness of breath.

» Lower risk for other lung disease (such as chronic obstructive pulmonary disease or COPD).

Remember, the best way to prevent lung cancer is to

STOP SMOKING.

If you currently smoke, talk to your health care professional or call the nationwide quit line at 1-800-QUIT-NOW (1-800-784-8669).

NEXT STEPS IF SCREENING IS RIGHT FOR YOU

Get a written order from your health care professional and go to the imaging facility listed below.

Name: ______________________________

Address: ______________________________

Phone: ______________________________

Email or Web site: ______________________________

Date of screening visit: ______________________________

AHRQ Pub. No. 16-EHC007-13-A
March 2016

APPENDIX F: DATA COLLECTION TOOL

ID	Age	Sex (Female/ Male)	Race (White, Black or AA, Other Pacific Islander, refused to respond or Undefined)	Ethnicity (Not Hispanic or Latino, Hispanic or Latino, Undefined)	Insurance (Medicaid/ Medicare)	Zip Code	Quarter Seen (Oct 19-Jan 18 or Jan 19- Apr 19)	Symptoms at presentation (Yes/ No)	Dual Eligibility (Yes/ No)	Cigarettes (Not smoker/ Smoker)	Pack-Years (<30 pack years, $\geq$ 30 pack years, not documented)	LCS Counseling (Yes/ No)	LDCT Referral Made (Yes/ No)	Other_Imaging (No, Abnormal baseline CXR, Abnormal baseline diagnostic CT, Abnormal following LDCT, not documented)	Smoking Cessation Counseling (Yes/ No)	Meets Criteria for LDCT Screening (Screened with LDCT, Meets criteria but NOT screened, Ordered by patient did not go; HCP offered LDCT but no documentation of pack years; Unable to verify if qualified- unknown pack years; Does NOT meet criteria- symptomatic; Does NOT meet cireria, <30 pack years; Does not meet criteria- Other; Already had LDCT screening ordered)

ID- Identification number
LCS- Lung cancer screening
LDCT- Low-dose chest tomography
CXR- Chest X-ray
CT- Chest tomography
HCP- Healthcare provider

APPENDIX G: ONE PAGER PDF LUNG CANCER SCREENING TOOL

RISK ASSESSMENT FOR LCDT LUNG CANCER SCREENING

- **Does the patient have BOTH NC Medicaid and are between the ages of 55-80 ? Yes or No**
  - If Yes, Continue
- **Calculate pack-years smoking with formula: # of years smoked X average number of packs smoked per day = pack years ___ (Number)**
  - Calculate Pack Years
- **Does the patient have at least a 30 Pack-Year history of cigarette smoking? Yes or No**
  - If Yes, Continue
- **Does the patient Currently smoke or they quit less than 15 years ago? Yes or No**
  - If Yes, Continue
- **Is the patient Asymptomatic of underlying lung cancer symptoms? Yes or No**
  - If Yes, Continue
- **Is the patient willing to undergo curative lung surgery? Yes or No**
  - If Yes, Continue
- **Has the patient received a low-dose CT lung screening in less than 12 months? Yes or No**
  - If No, Eligible for LDCT Referral

If patient meets all criteria above:

- Document required lung cancer screening shared-decision-making (SDM) conversation (risks vs. benefits)- G0296
- Document use of decision aid: "Is lung cancer screening right for me?" Agency for Healthcare Research and Quality (AHRQ)
- Document smoking cessation & abstinence counseling session- Z87.891 (ICD-10) (ICD-9-CM- V15.82)

Patient AGREES to have LDCT lung cancer screening: G0297

(not diagnostic CPT 71250)

- Written order for LDCT for lung cancer screening with required information documented (EMR)- Physician, NP, PA or CNS
- Beneficiary date of birth
- Actual pack-year smoking history (number)
- Current smoking status, and for former smokers, the number of years since quitting
- Statement that the beneficiary is asymptomatic
- National Provider Identifier (NPI) of the ordering practitioner
- Department of Radiology continues to obtain prior authorization for LDCT (EviCore prior authorization requirement)

Patient DECLINES LDCT lung cancer screening:

- Document rationale in EMR

Patient UNSURE of LDCT lung cancer screening:

- Schedule follow-up visit to discuss

WHY LUNG CANCER SCREENING MATTERS

- **Lung Cancer Statistics**
  - The American Cancer Society (2018) estimated that lung cancer accounted for 234,030 new cases and 154,050 deaths in 2018.
  - An estimated 8,888 North Carolinians were diagnosed with lung cancer and 6,168 people died from lung cancer in 2017 (North Carolina Cancer Prevention and Control Branch/ N.C. Comprehensive Cancer Control Program, 2017).
  - 85-90% of lung cancers are attributable to smoking (Centers for Disease Control, 2017).
  - North Carolina Medicaid enrollees, aged 16-64 years, report smoking rates at 43.3% (State Center for Health Statistics, North Carolina Department of Public Health, 2016).
- **Lung Cancer Statistics In Vance County, NC** *(1 of 100 Counties in North Carolina)*
  - Ranks 1st (highest) in current smoking rates (29% vs 21% in NC)
  - Ranks 14th in lung cancer mortality
  - Ranks 18th in distant stage at lung cancer diagnosis
  - Ranks in highest percent of population enrolled in NC Medicaid, ranging between 32-40%
- **Lung Cancer Risk Assessment & LDCT Screening**
  - 75% of lung cancers are Stage III or IV at diagnosis = 4% five-year survival rate (Siegel et al., 2017)
  - Despite endorsement by medical and nursing organizations and payers, LDCT screening guidelines have not been widely implemented in clinical practice as evidenced by low national lung cancer screening rates of only 1.9% (Pham et al., 2018).
  - North Carolina Medicaid enrollees with their high rates of smoking as well as associated health disparities, are at high risk for lung cancer (State Center for Health Statistics, North Carolina Department of Public Health, 2016).

This quality improvement initiative aims to improve the primary care provider's identification of North Carolina Medicaid enrollees at high risk for lung cancer and appropriately refer for LDCT screening in an effort to detect early-stage lung cancer and decrease lung cancer mortality.

APPENDIX H: BASELINE DEMOGRAPHICS

Table 1

Baseline Demographics, Eligibility for LDCT Screening and Smoking Cessation Counseling of Total Medicaid Practice Sample (Did Not Participate) Compared to Patient Sample

Demographic	Total Medicaid Practice Sample (N=150)		Patient Sample (N=34)		Results	
Patient Age (years)					T-Statistic	P-Value
Mean	61.89		66.47		4.910	0.000
Median	61.00		67.00			
Minimum	55		55			
Maximum	73		75			
Standard Deviation	4.87		5.03			
	n	%	*n*	%	Z-Score	P-Value
Gender						
Female	85	56.7	21	61.8	-0.543	0.589
Male	65	43.3	13	38.2	0.543	0.589
Race						
White/ Caucasian	63	42.0	27	79.4	-3.940	0.000
Black/ African American	81	54.0	7	20.6	3.521	0.000
Other/ Pacific Islander	2	1.3	0	0	0.677	0.497
Undefined/ Refused To Answer	4	2.7	0	0	0.963	0.337
Ethnicity						
Not Hispanic/ Not Latino	142	94.6	34	100	-1.377	0.168
Hispanic/ Latino	5	3.3	0	0	1.079	0.280
Undefined/ Refused To Answer	3	2.0	0	0	0.831	0.407

Insurance						
Medicaid	58	38.7	5	14.7	2.659	0.008
Medicare/ Dual Eligible	92	61.3	29	85.3	-2.659	0.008
Zip Code						
Within Vance County						
27536	69	46.0	17	50.0	-0.422	0.674
27537	39	26.0	6	17.6	1.023	0.308
Outside Vance County						
All others	42	28.0	11	32.4	-0.506	0.610
Eligibility for LDCT Screening						
Pack-Years						
<30 pack-years	4	2.7	11	32.6	-5.712	0.000
≥30 pack-years	28	18.7	23	67.6	-5.762	0.000
Not documented	118	78.7	0	0	8.635	0.000
Symptomatic	(N= 32)					
Yes	32	100	0	0	8.124	0.000
No	0	0	34	100	-8.124	0.000
Smoking Cessation Counseling of Current Smokers						
Yes	60	40.0	17	50	-1.067	0.285
No	87	58.0	17	50	0.850	0.395
Not Documented	3	2.0	0	0	0.831	0.407

P Significant at <0.05; Two tailed, two proportions Z-test

APPENDIX I: CONSORT DIAGRAM

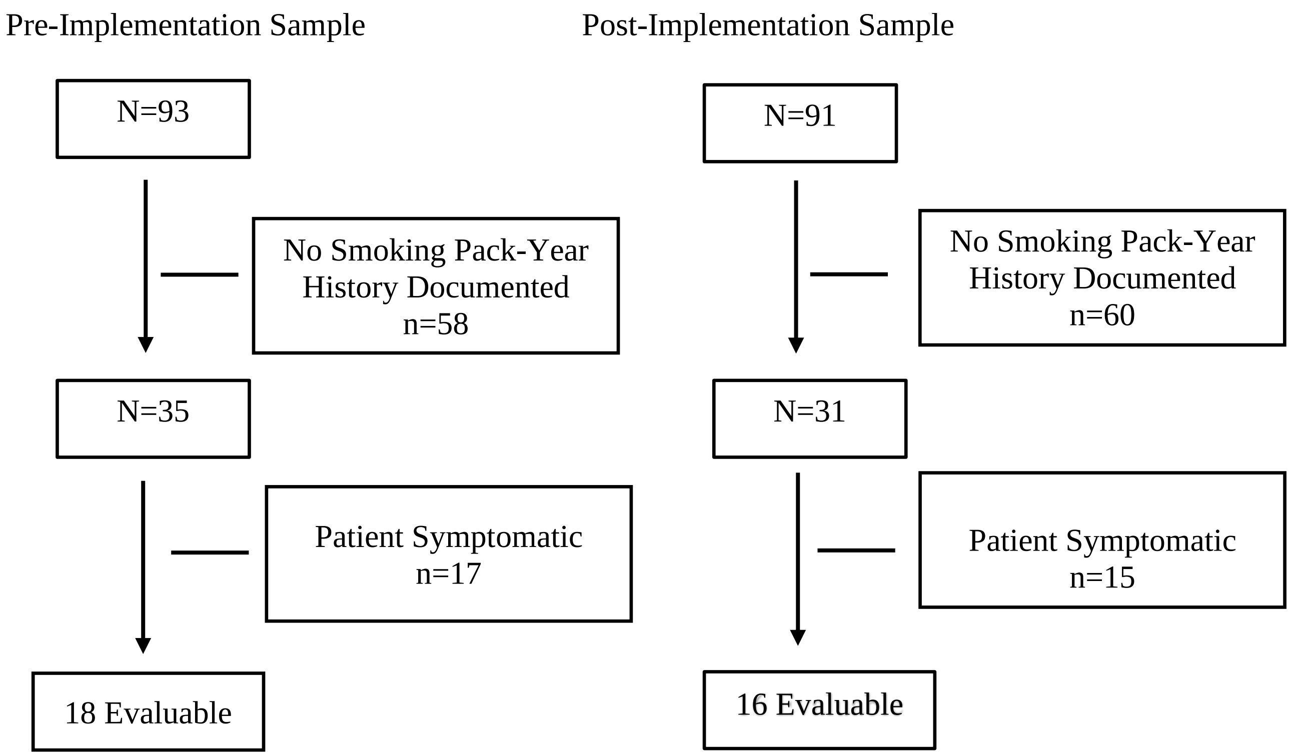


Figure 2. *Consort Diagram*

APPENDIX J: PATIENT SAMPLE DEMOGRAPHICS

Table 2

Patient Sample Demographics

Demographic	Total Patient Sample (N=34)		Pre-Implementation (N=18)		Post-Implementation (N=16)		Results	
Patient Age (years)							T-Statistic	P-Value
Mean	66.47		66.5		66.43		0.036	0.486
Median	67.00		67.00		67.00			
Minimum	55		55		55			
Maximum	75		75		75			
Standard Deviation	5.03		5.25		4.95			
	n	%	*n*	%	*n*	%	Z-Score	P-Value
Gender								
Female	21	61.8	11	61.1	10	62.5	-0.083	0.936
Male	13	38.2	7	39.8	6	37.5	0.0832	0.936
Race								
White/ Caucasian	27	79.4	3	38.9	4	25.0	-0.599	0.549
Black/ African American	7	20.6	15	83.3	12	75.0	0.599	0.549
Other/ Pacific Islander	0	0	0	0	0	0	0	0
Undefined/ Refused To Answer	0	0	0	0	0	0	0	0
Ethnicity								
Not Hispanic/ Not Latino	34	100	18	100	16	100	0	1
Hispanic/ Latino	0	0	0	0	0	0	0	0
Undefined/ Refused To Answer	0	0	0	0	0	0	0	0
Insurance								
Medicaid	5	14.7	2	11.1	3	18.8	-0.628	0.529
Medicare/ Dual	29	85.3	16	88.9	13	81.3	0.627	0.529

Eligible								
Zip Code								
Within Vance County								
27536	17	50.0	8	44.4	9	56.3	-0.687	0.49
27537	6	17.6	3	16.7	3	18.8	-0.159	0.873
Outside Vance County								
All others	11	32.4	7	38.9	4	25.0	0.864	0.39

P Significant at <0.05; Two tailed, two proportions Z-test

APPENDIX K: PATIENT SAMPLE ELIGIBLE FOR LDCT SCREENING

Table 3

Patient Sample Eligible for LDCT Screening

	Total Patient Sample (N= 34)		Pre-Implementation (N=18)		Post-Implementation (N=16)		Results of Two Proportion Z-Test	
	n	%	*n*	%	*n*	%	Z-Score	P-Value
Pack-Years								
<30 pack-years	11	32.6	6	33.3	5	31.3	0.129	0.897
≥30 pack-years	23	67.6	12	66.7	11	68.8	-0.129	0.897
Not documented	0	0	0	0	0	0	0	0
Symptomatic	(N= 34)		(N=18)		(N=16)			
Yes	34	100	0	0	0	0	0	0
No	0	0	18	100	16	100	0	0

P significant at <0.05; Two tailed, two proportions Z-test

APPENDIX L: PATIENT SAMPLE SMOKING CESSATION COUNSELING

Table 4

Patient Sample Smoking Cessation Counseling

	Total Sample (N=34)		Pre-Implementation (n=18)		Post-Implementation (n=16)		Results of Two Proportions Z-Test	
	n	%	n	%	n	%	Z-Score	P-Value
Smoking Cessation Counseling of Current Smokers								
Yes	17	50	9	50	8	50	0	1
No	17	50	9	50	8	50	0	1
Not Documented	0	0	0	0	0	0	0	0

P Significant at <0.05; Two tailed, two proportions Z-test

APPENDIX M: PATIENT SAMPLE OUTCOMES FOR LDCT SCREENING REFERRAL

Table 5

Patient Sample Outcomes for LDCT Screening Referral

	Total Sample (N=34)		Pre-Implementation (N=18)		Post-Implementation (N=16)		Results of Two Proportions Z-Test	
	n	%	*n*	%	*n*	%	Z-Score	P-Value
Referred for LDCT Screening	4	12	1	5.6	3	19	-1.192	0.234
Not Referred for LDCT Screening	19	56	11	61.1	8	50	0.651	0.512
Referred and Declined LDCT Screening	0	0	0	0	0	0	0	0

P significant at <0.05; Two tailed, two proportions Z-test

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