LUNG CANCER SCREENING: IDENTIFICATION OF HIGH-RISK PATIENTS AND SHARED DECISION-MAKING

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Teresa Dianna Formo

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The Supervisory Committee certifies that this ***disquisition*** complies with North Dakota State University's regulations and meets the accepted standards for the degree of

DOCTOR OF NURSING PRACTICE

SUPERVISORY COMMITTEE:

Dr. Kelly Buettner-Schmidt
Chair

Dr. Dean Gross

Dr. Christopher Whitsel

Dr. Tara Brandner

Approved:

March 31, 2020
Date

Dr. Carla Gross
Department Chair

ABSTRACT

Lung cancer is the most common cause of cancer-related deaths in the United States. Prevention and early detection of lung cancer are imperative in decreasing lung cancer mortality. Screening for lung cancer with low-dose computed tomography (LDCT) decreases lung cancer by 20%. Several organizations introduced lung cancer screening (LCS) guidelines in 2013, including Centers for Medicare and Medicaid (CMS) and the United States Preventive Services Task Force. However, LCS participation for eligible patients remains low, due in part to the complexity of the LCS process.

The goal of this practice improvement project was to increase the knowledge of rural primary care providers regarding LCS guidelines and the related CMS requirements and to increase their confidence in initiating shared decision-making (SDM) discussions. An educational intervention consisting of a LCS educational session and a toolkit was implemented in two rural clinics. Providers at both clinics reported a benefit to the educational intervention.

Pre-, immediate post-, and two-month post-education surveys were collected to evaluate the impact of the educational intervention, including provider knowledge of LCS guidelines and CMS requirements, and confidence in SDM. Project results demonstrated an increased knowledge of LCS guidelines and CMS requirements with the greatest knowledge at immediate post-education and a high level of knowledge remaining at two months post-education. A small, nonsignificant, increase in provider confidence in initiating SDM discussions occurred.

At both clinics, data collected through chart audit demonstrated an improvement in documentation needed to determine LCS eligibility and increased the percentage of patients identified at high risk for lung cancer and thus, eligible for LCS. At one clinic these changes were significant. The data were further examined for SDM discussions and referrals for LDCT or

to specialist for LCS with one clinic increasing SDM documentation and LDCT referrals post-education. In conclusion, although further research is needed in implementation processes of LCS, specifically in consistent documentation to improve determination of LCS eligibility of patients, this practice improvement project found education increased provider knowledge and ability to complete requirements needed to improve LDCT screenings for lung cancer.

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To a class as we finish this journey, we may have all traveled a similar, yet different path to come to where we are now and to where we may go in the future. I am grateful to each and every classmate for the individual differences that have enhanced my education. I have learned lessons from each and everyone. Finally, I want to give glory to Jesus Christ for helping me with this project, for providing insight when I needed it the most, and for allowing me to use my God given talents in caring for others. This verse that carried me through this project: *"For with God nothing shall be impossible."* Luke 1:37.

DEDICATION

This dissertation is dedicated to my family.

My husband Shawn, for the support, laughs, encouragement and understanding. I am forever grateful to have you by my side as we traveled this journey and continue our future adventures.

To my children and grandchildren. Your understanding for missed visits, holidays and get togethers. Three years has passed fast, yet I am forever grateful for the understanding in letting your mom realize a dream.

To my parents, time is something you can never get back, with the completion of this journey, my hope is to spend more time with you. I am thankful you raised me to go after my dreams, no matter when.

"Be strong and courageous, all you who put your hope in the Lord." Psalms 31:24

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LIST OF ABBREVIATIONS

ACS	American Cancer Society
SEER	Surveillance, Epidemiology, and End Results Program
CXR	Chest Radiograph
LCS	Lung Cancer Screening
NLST	National Lung Screening Trial
LDCT	Low-Dose Computed Tomography
USPTF	United States Preventive Task Force
SDM	Shared Decision-Making
AMC	Ashley Medical Center
CMS	Centers for Medicare and Medicaid Services
CDC	Center for Disease Control and Prevention
NSCLC	Non-Small Cell Lung Cancer
SCLC	Small-Cell Lung Cancer
DANTE	Detection and Screening of Danish Lung Cancer Screening Trial
DLCST	Danish Lung Cancer Screening Trial
VHA	Veterans Health Administration
ACA	Affordable Care Act

CHAPTER ONE. INTRODUCTION

Background and Significance

Lung cancer is the most common cause of cancer-related deaths and the second most common cancer for both men and women in the United States (American Cancer Society [ACS], 2019a). Despite occurring at similar rates to breast, prostate, and colorectal cancer, lung cancer accounts for three to four times more deaths (Detterbeck, Mazzone, Naidich, & Bach, 2013). For 2019, the ACS estimates there will be 228,150 new lung cancer diagnoses and 142,670 lung cancer-related deaths in the United States (ACS, 2019b). Although the incidence and mortality rates of lung cancer have slowly declined over the past decade, the overall five-year survival rate remains low (Mazzone et al., 2015). Moreover, for 2019, the ACS (2019b) estimates that 300 deaths in ND and 410 deaths in SD, will be attributed to lung cancer. In 2018, the estimated expenditure for lung cancer care in the United States was over $14 million, with an additional $36 billion loss in productivity related to lung cancer deaths (National Cancer Institute, 2018).

The stage of cancer diagnosis refers to the extent of cancer in the body and is the most substantial influence on the length of survival and treatment option. When diagnosed before metastasis, lung cancer five-year survival rates are considerably higher than the overall survival rates (Surveillance, Epidemiology, and End Results Program [SEER], 2018). Unfortunately, most lung cancer diagnoses are made at an advanced or metastatic stage, resulting in a high rate of lung cancer mortality (Patz et al., 2016). Localized lung cancer is most often asymptomatic, leading to a delay in diagnosis. More often, the patient presents with symptoms, or in an advanced stage, contributing to the high mortality rate (Moyer, 2014).

Major risk factors for lung cancer include increasing age and cumulative exposure to tobacco smoke. In fact, it may take as long as two decades for lung cancer to develop, putting

both current and former smokers at risk (Manser et al., 2013). This makes screening for lung cancer challenging. As early as 1970, studies using chest radiograph (CXR), with or without sputum cytology, for lung cancer screening (LCS) were conducted and failed to show a statistically significant decrease in lung cancer mortality (Wender et al., 2013). Released in 2010, the results of the National Lung Screening Trial (NLST, 2011) showed a 20% reduction in lung cancer mortality rates for high-risk patients screened with annual low-dose computed tomography (LDCT). These results were a defining moment for LCS and prompted the development of LCS guidelines.

In 2013, the ACS and United States Preventive Task Force (USPTF) released guidelines recommending annual LDCT for LCS in adults with a significant history of smoking (Eberth, 2015; Moyer, 2014). Several systematic reviews have evaluated the effectiveness, risks, and benefits of LCS with LDCT (Bach et al., 2012; Boiselle, 2013; Humphrey et al., 2013; Manser et al., 2013; Slatore, Sullivan, Pappas, & Humphrey, 2014). In addition to the demonstrated effectiveness of LDCT in reducing lung cancer mortality, the following associated harms were identified and discussed later in this paper: incidental findings, false-positives, invasive procedures, over-diagnosis, and radiation exposure (Wender et al., 2013). Based on findings of benefits and harms, Wender et al. (2013) determined that more data are needed to assess the cost-effectiveness of LCS with LDCT. Mazzone et al. (2018) found LCS to be a balance of benefits and harms. A thorough understanding of the screening process by providers is essential to optimize the benefits of LCS.

Prevention and early detection of lung cancer are vital for decreasing lung cancer mortality (Wood et al., 2018). However, LCS is a complex process beginning with the

identification of eligible individuals (Ramsey et al., 2015). Research has shown that very few eligible individuals have been screened for lung cancer (Huo, Shen, Volk, & Shih, 2017).

An integral part of LCS is shared decision-making. Shared decision-making (SDM) is a process between healthcare providers and patients to facilitate decisions based on clinical evidence and the patient's values (Politi, Wolin, & Legare, 2013). The process acknowledges individual values and beliefs, allowing the patient to become an active partner with their provider in reaching a mutually agreeable decision (Carter-Harris, Tan, Salloum, & Young-Wolff, 2016). During the SDM discussion, the potential harms and benefits of LCS are discussed with eligible patients (Carter-Harris et al., 2016).

Reimbursement of LCS by the Centers for Medicare and Medicaid Services (CMS) requires documentation of SDM discussion and counseling for smoking cessation (CMS, 2015). Mishra et al. (2016) noted an overall patient lack of awareness for LCS with LDCT, emphasizing the importance of SDM visits. Additionally, SDM discussions are complicated by provider perceived barriers and provision of inconsistent information to patients (Wiener et al., 2018).

Application of evidence-based practices for LCS is lacking in rural areas. Rural providers are often faced with limited resources, decreased access, and lack of awareness of recommended guidelines (Jenkins et al., 2018). This co-investigator's clinical rotations in the rural settings of Ashley Medical Center Clinic (AMC) in Ashley, North Dakota (ND) and Redfield Clinic in Redfield, South Dakota (SD), provided the opportunity for initial observations relating to the identification of patients eligible for LCS and SDM discussions. Both facilities assessed patients' smoking status and the amount smoked. This data were documented in the patient's record. However, documentation of pack-years and eligibility for LCS was inconsistent. In addition, no SDM discussions or referrals for LDCT for LCS were observed. Based on the USPSTF grade B

recommendation and CMS support for annual screening, key providers at the clinics verified the need to implement LCS guidelines. Education involving LCS guidelines and SDM were requested by stakeholders at both clinics as part of the implementation strategy.

Problem Statement

In 2015, the CMS announced reimbursement for annual LCS for high-risk patients to increase early detection of lung cancer and subsequently decreasing lung cancer mortality (CMS, 2015). Several articles have described considerations for the implementation of LCS guidelines (Mazzone et al., 2015; Mazzone et al., 2018; Ramsey et al., 2015; Wiener et al., 2018). According to Hoffman et al. (2015), overall awareness and knowledge of LCS guidelines by both the patient and provider hindered the implementation of the screening guidelines in the rural setting. This lack of knowledge directly affects the SDM process, creating another barrier to guideline implementation (Mishra et al., 2016).

Purpose

The purposes of this practice improvement project was (a) to increase the knowledge of rural primary care providers regarding LCS guidelines and the related CMS requirements and to increase their confidence in initiating SDM discussions through the development and implementation of LCS education and (b) to determine the impact of the project.

Objectives

The project objectives were as follows:

1. Develop and implement an educational intervention consisting of an education session and lung cancer screening toolkit, regarding lung cancer screening and the CMS required shared decision-making discussion elements to improve the use of published lung cancer screening guidelines by providers.

2. Determine the impact of the intervention by assessing for an:
    a. Increase in the knowledge of rural primary care providers regarding lung cancer screening guidelines and the related CMS requirements for lung cancer screening and shared decision-making discussions.
    b. Increase in the confidence of rural primary care providers initiating shared decision-making discussions.
    c. Increase number of patients identified at high-risk for lung cancer and eligible for lung cancer screening by rural primary care providers.
    d. Increase number of shared decision-making discussions, inclusive of all required elements, initiated between rural primary care providers and patients at high-risk for lung cancer.
    e. Increase number of referrals for low-dose computed tomography or to specialist for lung cancer screening in eligible high-risk patients by rural primary care providers.

CHAPTER TWO. LITERATURE REVIEW AND THEORETICAL FRAMEWORK

A literature search was conducted to review evidence regarding a) lung cancer; b) morbidity and mortality rates; c) recommended screening methods; d) barriers to LCS; e) provider knowledge of LCS guidelines; and f) SDM. The search was conducted using the Web of Science, Cochrane, PubMed, and MEDLINE databases for articles published from January 2013 to April 2019. An additional search was conducted to review additional evidence published from April 2019 through January 2020.

Search criteria included peer-reviewed journals, full-text articles published in the English language, including clinical trials, review, systematic reviews, and evidence-based clinical guidelines. Keywords used in the search included "*lung cancer screening guidelines*" AND "*shared decision making*", "*lung cancer screening implementation*" AND "*primary care*". An additional review of relevant grey literature, including factsheets, governmental documents, and committee reports was conducted. A secondary search of reference lists was also reviewed for possible inclusion (see Appendix A for search strategy).

Disease Presentation

Increasing age and cumulative exposure to tobacco smoke are major risk factors for lung cancer. Smoking is the leading modifiable risk factor for lung cancer and is responsible for 81% of all lung cancer deaths (ACS, 2019a). The Center for Disease Control and Prevention (CDC) (2018) reported that smokers are 15 to 30 times more likely to be diagnosed with lung cancer or die from lung cancer than non-smokers. Current or former smokers make up roughly 37% of adults in the United States, despite diligent efforts toward smoking cessation and an overall decline in smoking rates (Moyer, 2014). As with most cancers, the incidence of lung cancer increases with age. In the United States, the average age for lung cancer diagnosis is

approximately 70 years old, with less than 10% occurring in individuals less than 50 (Lung Cancer Alliance, 2019).

According to the CDC (2018), lung cancer is ranked as the third most common cancer in ND, behind breast and prostate cancer. In 2016, the incidence of lung cancer in ND was 53.6 per 100,000 people with a mortality rate of 34.6 per 100,000 people, ranking lung cancer the highest cause of cancer death. Closely resembling ND, lung cancer in SD is also ranked the third most common cancer and the most common cause of cancer death. In 2016, the incidence of lung cancer in SD was 58.2 per 100,000 people with a mortality rate was 39.4 per 100,000 people.

Most lung cancer is categorized into non-small cell lung cancer (NSCLC) and small-cell lung cancer (SCLC). NSCLC makes up 85% of all lung cancer cases and is further classified as adenocarcinoma (41% of lung cancer cases); squamous cell and transitional cell carcinoma (21%); large cell carcinoma (3%); and not otherwise specified (20%) (Howlader et al., 2018). This categorization is the basis for the management, prognosis, and screening efficacy of lung cancer. Commonly occurring in the larger airways, SCLC is characterized as aggressive cancer with early metastasis, making detection difficult (Nanavaty, Alvarez, & Alberts, 2014). Whereas, NSCLC is found in the peripheral lung tissue, allowing for easier detection through screening, contributing to the increased five-year survival rates (Howlader et al., 2018).

The ACS (2019a) has reported that approximately 57% of lung and bronchus cancer is diagnosed after or at the point of metastasis. This contrasts with the 16% diagnosed in a localized stage. When diagnosed early, the five-year survival rate of lung cancer is 57%, considerably higher than the overall lung cancer five-year survival rate of 18% (SEER, 2018). Patients diagnosed with localized lung cancer have the best chance for cure or long-term-survival with

surgical resection, endorsing the need for screening and early detection (Rai, Doria-Rose, Silvestri, & Yabroff, 2019).

Lung Cancer Screening

Lung cancer treatment success is associated with the stage at the time of diagnosis. Strategies to decrease lung cancer mortality include treatment, prevention, and early detection. Undoubtedly, prevention is the most crucial strategy with smoking cessation verified as the most effective intervention (Richards, White, & Caraballo, 2014). Moreover, screening with LDCT has shown that diagnosis at an early stage improves overall survival rate and clinical outcomes (Wender et al., 2013). The goal of any screening is to decrease mortality without causing harm and early detection of lung cancer through screening has shown promise in reducing lung cancer mortality (Detterbeck et al., 2013).

Early LCS research examined the use of CXR, with or without sputum cytology, to identify early lung cancer and subsequently reduce lung cancer mortality (De Koning et al., 2014; Humphrey et al., 2013). Wender et al. (2013) reported that four random control trials (RCT) failed to show a statistically significant reduction in mortality and as a result, the ACS removed the recommendation to screen current and former smokers with CXR. Whereas, several studies have demonstrated the effectiveness of LDCT in detecting early-stage lung cancer (Bach et al., 2012; De Koning et al., 2014; Horeweg et al., 2014; Humphrey et al., 2013; Infante et al., 2015; Kandora, Silvestri, & Tanner, 2015; Manser et al., 2013; Patz et al., 2016; Slatore et al., 2014; The NLST Research Team, 2011; Wille et al., 2016).

The NLST (2011), the largest RCT published to date, included 53,434 participants in 33 centers across the United States. The results of the trial found that screening with LDCT reduced the relative risk of death from lung cancer by 20% (95% CI, 6.8-26.7; $p = .004$) when compared

to screening with CXR (NLST, 2011). The results concluded that in order to prevent one death from lung cancer, 320 individuals would need to be screened with LDCT. These findings are similar to the number of women greater than 50 years of age that needed to be screened with mammography to prevent one death from breast cancer (Kandora et al., 2015).

Early results from the Dutch Belgian Lung Cancer Screening trial (NELSON), the second largest RCT, suggested that screening with LDCT decreased lung cancer mortality by greater than 25% (De Koning et al., 2014; Kandora et al., 2015). The smaller NELSON study randomized 15,822 participants and compared screening for lung cancer with LDCT to no screening. Final results for the NELSON study, released during the International Association for the Study of Lung Cancer concluded that overall, LDCT scanning decreased mortality by 26% in high-risk men and 61% in high-risk women over a 10-year period, confirming the value of LDCT screening for lung cancer in high-risk individuals (De Koning, Van Der Aalst, Ten Haaf, & Oudkerk, 2018).

Other trials, including two European trials, failed to show a positive effect of LDCT on lung cancer mortality (Infante et al., 2015; Wille et al., 2016). The Detection and Screening of Early Lung Cancer by Novel Imaging Technology and Molecular Essays (DANTE) trial and the Danish Lung Cancer Screening Trial (DLCST) compared annual LDCT with usual care. The smaller study populations and lower risk groups screened in these trials attributed some of the differences when compared to the NLST (Mazzone et al., 2018).

Benefits of Lung Cancer Screening

As discussed previously, the most important benefit of LCS is early detection and a reduction of lung cancer mortality rate. The results of the NLST and NELSON trial demonstrated a reduction in lung cancer mortality with annual LDCT screening of high-risk

individuals (De Koning et al., 2018; NLST, 2011). The benefits of LDCT screening are personalized, with individuals at the highest risk for lung cancer being most likely to benefit from screening (Moyer, 2014). Screening with LDCT leads to an increase in early detection of lung cancer and a better prognosis.

Smoking cessation is the most effective method in preventing lung cancer and decreasing lung cancer mortality. The effect of LDCT screening on smoking cessation or reinitiation has not been substantiated (Bach et al., 2012). Still, LCS provides an opportunity to educate current smokers on smoking cessation. There is some data indicating a positive effect of LDCT screening on smoking cessation in individuals (Richards et al., 2014). Mishra et al. (2016) reported that participating in LCS with LDCT is not by itself a strong disincentive to smoking. They found that a positive finding provided motivation to stop smoking, and even more so after viewing a lung nodule, however a negative finding is not sufficient to encourage smoking cessation. However, some studies have suggested that LDCT screening may result in continued smoking as individuals feel protected by the screening (Mazzone et al., 2018).

Nevertheless, the effect of screening as motivation to stop smoking has not been established. No difference in smoking cessation rates was found in the LDCT screening and control groups in the DLCST and NELSON trials; however, higher smoking cessation rates in the LDCT group were noted for the UK Lung Cancer Screening Trial (Mazzone et al., 2018). More recently, Huo et al. (2019) found no association with any change in smoking behavior in the six months following LCS. However, smoking cessation remains an integral part of LCS guidelines and is required by CMS as part of LDCT lung cancer screening (CMS, 2015; Mishra et al., 2016).

Risks of Lung Cancer Screening

Although LCS with LDCT show promise in reducing lung cancer mortality, LDCT is not without risks. Several studies have identified harms from LCS with LDCT (Bach et al., 2012; Humphrey et al., 2013, Mazzone et al., 2018; Moyer, 2014; National Comprehensive Cancer Network [NCCN], 2019). The most commonly discussed harms are related to the identification and evaluation of lung nodules, including false positive results, the significance of incidental findings unrelated to lung cancer, the possibility of overdiagnosis and overtreatment of lung cancer, the effects of cumulative radiation exposure, and the psychological effects of these findings. Understanding the impact of LCS harms are important in-patient discussions. Arenberg (2019) found that harms of screening are often both overestimated and underestimated by poorly informed patients and providers.

False Positives

The most discussed risk associated with LCS is the high rate of false-positive results. Approximately 95% of all positive screening results do not result in cancer diagnosis (Moyer, 2014). A false-positive result can lead to further testing and invasive procedures, increasing distress, and cost (NCCN, 2019). The NLST (2011) reported a false-positive rate of 96% in the CT screening group with a cumulative risk of a false-positive result of 33% with two annual screenings. In studies reviewed by Humphrey et al. (2013), the majority of invasive procedures were performed for cancer with a positive predictive value ranging from 50% to 92%. Arenberg (2019) reported an increasing number of invasive procedures in routine practice as compared to the clinical trial. This finding stresses the need for strategies to reduce the number of invasive procedures used to investigate screening detected nodules.

Incidental Findings

Incidental findings commonly identified with LDCT include coronary artery calcification, emphysema, bronchiectasis, pulmonary fibrosis, and carcinoid tumors (Moyer, 2014). Mazzone et al. (2018) reported the prevalence of incidental findings ranging from 41% to 94% on initial scans. Approximately 40% of veterans screened in the Veterans Health Administration (VHA) demonstration project reported incidental findings (Kinsinger et al., 2017). Incidental findings require health providers time to determine if additional testing is required, and the value of these findings has not been defined. Incidental findings and false positives can lead to emotional distress, invasive procedure and additional testing in patients (Boiselle, 2013; Wender et al., 2013). However, evidence of the harms associated with incidental findings has not been established (Moyer, 2014).

Overdiagnosis

Although no studies have officially reported overdiagnosis, results from the NLST found 119 more lung cancer cases in the LDCT group than the CXR group after more than six years of follow-up, suggestive of some overdiagnosis (Humphrey et al., 2013). Overdiagnosis with LDCT screening can result in unnecessary treatment and therapy, potentially inflicting harm on the patient (Moyer, 2014). The impact of overdiagnosis is affected by the definition used. A standard definition of overdiagnosis is histologically confirmed clinically insignificant cancers. In other words, lung cancer, that if not identified through screening and left untreated, would not have affected the patient (Bach et al., 2012). Mazzone et al. (2018) describe an extension of this definition to include any lung cancer diagnosed in a patient with comorbidities leading to death before the cancer affected their well-being. Otherwise stated, by extension, an early lung cancer detected through screening may not affect an individual that died during the early asymptomatic

stage of lung cancer. This further emphasizes the significance in selecting patients for screening without comorbid conditions that overshadow the risk of lung cancer related death.

Radiation Exposure

Frequent or repeat LDCT screening increases an individual's exposure to radiation. In comparison, radiation exposure associated with LDCT is close to the exposure associated with mammography (Humphrey et al., 2013). Harms associated with radiation exposure include cancer from cumulative exposure to radiation. The amount of exposure varies depending on the number of scans and other sources of radiation (Moyer, 2014). Also, the risk of radiation exposure is related to the age when screening begins and the sex of the patient (Mazzone et al., 2018). Prediction models using NLST data have estimated one radiation caused cancer death for every 2500 persons screened, illustrating that the benefit of preventing lung cancer mortality is greater than the radiation risk (Bach et al., 2012).

Psychological Effects

Little research is available to support or refute effects on quality of life from LCS (NCCN, 2019). A systematic review by Slatore et al. (2014), identified three studies (two RTCS and one cohort) that evaluated the effect of LDCT lung cancer screening on patient-centered outcomes. Individuals with positive or indeterminate results experienced a short-term increase in distress and anxiety, with no long-term differences reported. In comparison to other cancer screenings, these findings were similar to patients with negative mammograms.

Consequently, the review noted that non-participants in one study (DLSCT) had more negative psychosocial characteristics than participants (Slatore et al., 2014). Overall, the evidence was of fair quality, and at best suggests that LCS with LDCT is associated with short-term psychologic discomfort and false-positive results are connected to slight increases in

distress. Mazzone et al. (2018), confirmed that the detection of nodules during screening might transiently increase distress without an adverse effect on anxiety levels. Distress can be alleviated in both participants and non-participants by decreasing false positives and increasing communication strategies to ensure the provision of adequate information, consideration of individual values and preferences, and SDM.

Lung Cancer Screening Recommendations

The most important part of a screening program is the identification of individuals who will benefit the most from the screening interventions and experience the least amount of harm. The increasing risk of lung cancer is directly related to cumulate exposure to tobacco and age (Humphrey et al., 2013). The NLST demonstrated the best evidence for the benefit of screening. Participants in the trial were 55 to 74 years with a 30 pack-year smoking history; and included both current smokers and former smokers who have quit within the past 15 years (NLST, 2011). The participants were screened annually for three years, making the oldest participant 77 years old.

With the 2011 release of the NSLT report, several organizations updated or developed LCS recommendations. Although guidelines differ, eligibility for screening is similar to the inclusion criteria of the NLST for all the recommendations (see Table 1). The NLST participants, compared to the general US population eligible for LCS, were found to be younger, had a higher level of education, more likely to be a former smoker, and less likely to be a member of a minority group (Kandora et al., 2015). Additional risk factors for lung cancer, including asbestos exposure, secondhand smoke exposure and radon exposure are difficult to quantify into existing lung cancer risk models (Arenberg, 2019). As such, current recommendations for lung cancer screening eligibility in the guidelines do not include other causes of lung cancer.

Table 1

Lung Cancer Screening Guideline Recommendations.

Organization	Age in years	Recommendation
USPSTF[a]	55 - 80	≥ 30 pack-year current or former smoker with smoking cessation within past 15 years
ACCP/ASCO[b]	55 – 74	≥ 30 pack-year current or former smoker with smoking cessation within past 15 years
AATS[c]	55 – 79	≥ 30 pack-year smoking history
	Until 79	> 5-year lung cancer survivor without recurrence
	50 – 79	≥ 20 pack-year smoking history and added risk of developing lung cancer ≥ 5% in 5 years
NCCN[d]	55 – 74	≥ 30 pack-year current or former smoker with smoking cessation within past 15 years
	≥ 50	≥ 20 pack-year current or former smoker and one additional risk factor other than secondhand smoke
ACS[e]	55 – 74	≥ 30 pack-year current or former smoker with smoking cessation within past 15 years and in relatively good health
ALA[f]	55 – 74	≥ 30 pack-year current or former smoker with smoking cessation within past 15 years

[a] USPSTF, United States Preventive Services Task Force (Moyer, 2014)
[b]ACCP, American College of Chest Physicians; ASCO, American Society of Clinical Oncology (Detterbeck et al., 2013)
[c]AATS, American Association of Thoracic Surgeons (Jaklitsch et al., 2012)
[d] NCCN, National Comprehensive Cancer Network; additional risk factor includes chronic obstructive pulmonary disease, environmental/occupational exposure, prior cancer/radiation therapy and general family history (Wood et al., 2018)
[e]ACS, American Cancer Society (Wender et al., 2013)
[f]ALA, American Lung Association (ALA, 2018)

The USPSTF conducted a thorough systematic review of LCS evidence and applied modeling studies to the various screening recommendations. Based on these findings, the USPSTF projected a substantial balance of benefits and harms with annual LDCT screening of adults at high risk for lung cancer (Humphrey et al., 2013). Arenberg (2019) stated "the importance of this modeling is that the eligible population of smokers in the US is different from the subjects in the NLST" (p.S78). De Koning et al. (2018) reported that approximately 50% of lung cancer cases would be detected at an early stage with annual LDCT screening for individuals ages 55 through 80 years with a 30 pack-year smoking history; this includes current smokers or former smokers who quit within the past 15 years.

The USPSTF (2013) issued a Grade B recommendation for LCS indicating that "there is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial" (recommendation summary section). Per the USPSTF (2013), screening should discontinue once a person has not smoked for 15 years, develops a health problem that limits life expectancy, or inability or unwillingness to have curative lung surgery. In 2015, in response to the USPSTF's Grade B recommendation, the CMS-approved reimbursement of LCS with LDCT for high-risk patients (CMS, 2015). Refer to Appendix B for CMS lung cancer screening requirements.

An estimated 12,000 lung cancer-related deaths per year can be attributed to the low uptake of LCS guidelines and underscreening (Jemal & Fedewa, 2017). In fact, the 2015 National Health Interview Survey noted that only 5% of eligible individuals had been screened for lung cancer (Huo et al., 2017). Challenges in the implementation of LCS with LDCT identified in a recent VHA study included difficulty in identifying patients eligible for screening (Kinsinger et al., 2017).

In another study, Lewis et al. (2019), surveyed 625 providers in an academic medical center and compared providers knowledge of LCS guideline and LDCT referrals. Results of the survey found that providers with low LCS knowledge were less likely to order LDCT. A noteworthy finding of the study is the current low knowledge of LCS guidelines. Substantiating the need for additional provider education. Knowledge was measured as a continuous variable based on the number of correct LCS guideline knowledge questions. Knowledge of initial screen age of 55, both current and former smoking status, annual screening interval, and no LCS recommendation for patients unable to undergo surgery were the most strongly associated with LDCT order / referral.

Several articles have described considerations for the implementation of LCS guidelines (Mazzone et al., 2015; Mazzone et al., 2018; Ramsey et al., 2015; Wiener et al., 2018). In primary care, a standardized approach should include the question of who to screen; identification of eligible patients; how to conduct an SDM visit; communication and management of LDCT results; and incorporation of smoking cessation (Mazzone et al., 2018). This approach is congruent with Ramsey et al. (2015) findings, which identified several components to successful lung cancer screening, including correctly identifying individuals eligible for selection; providing access to screening; ensuring appropriate follow-up of positive and negative screening results; and offering smoking cessation support. Counseling on the risks and benefits of lung cancer screening, as well as smoking cessation, should be provided to all individuals identified as high-risk for lung cancer and eligible for LCS.

Ramsey et al. (2015) described primary care providers as ideally positioned to identify high-risk eligible patients and conduct SDM visits. Most primary care providers currently collect patient's smoking status as part of CMS's meaningful use core measures. Documenting smoking history, including how much and how long a patient has smoked, appears to be a logical extension of this history.

Shared Decision-making

Considering the high percentage of false-positive results and commitment to follow-up associated with LCS; the risks and benefits of screening should be thoroughly discussed with eligible individuals before LDCT screening (De Koning et al., 2014). The CMS recognizes the importance of SDM, and in fact, LCS was the first cancer screening modality in which the CMS required documentation of an SDM visit for reimbursement (Carter-Harris et al., 2016). Bryne,

Thurer, and Studts (2019), found that presenting information in a comprehensible, relevant manner to elicit patient preferences is important aspect of SDM.

Lung cancer screening guidelines recommend an informed or SDM discussion regarding the benefits of LCS, limitations, known harms, and potential harms (Detterbeck et al., 2013; NCCN, 2019; Moyer, 2014; Wender et al., 2013). Likewise, the SDM visit should include the determination of eligibility for LCS (Mazzone et al., 2018). The SDM discussion should inform patients that undergoing LDCT may not prevent lung cancer death or identify all lung cancers (NLST, 2011). High-risk individuals should be counseled about false-positive results, and that a positive test does not mean they have lung cancer and may require further testing (Wiener et al., 2018).

Patients should understand that LCS is an ongoing process and commitment to the follow-ups are an essential part of the screening process (NCCN, 2019). Moreover, patients should be aware that LCS is not recommended if they are unable or unwilling to have curative therapy because of health or other significant problems (Moyer, 2014). Early diagnosis of lung cancer has less of an impact on a patient with a significant comorbid disease limiting life expectancy (Arenberg, 2019). The patient assessment should include a functional status assessment to determine if patients can survive or are willing to undergo lung cancer treatment. The number needed to screen to prevent one death for lung cancer and breast cancer are comparative. However, if treatment is not followed after a positive screening, the patient's cancer has not been deterred, negatively affecting the efficacy of LCS (Erkmen et al., 2017).

Despite recommendations for SDM, several studies have reported variable use and an inconsistent inclusion of patient preferences (Carter-Harris et al., 2016; Kandora et al., 2015; Lowenstein et al., 2019; Wiener et al., 2018). A qualitative study by Lowenstein et al. (2019),

found that patients and providers perceived LCS and SDM differently. In their study, patients, strongly influenced by emotional factors, were more likely to emphasize the benefits and minimize the risks of LCS. Conversely, providers in the study placed greater emphasis on potential harms.

Recent studies have demonstrated limited use of SDM and included only minimal information on the harms of screening (Brenner et al., 2018; Wiener et al., 2018). Carter-Harris et al. (2016) found that current smokers, individuals with a family history of cancer, and individuals with health care coverage were more likely to report SDM discussions with their providers. Risk prediction models, developed for the determination of individuals at the highest risk for lung cancer, can be used to educate patents in understanding the individual risk for lung cancer and help them make informed decisions (Kandora et al., 2015).

Shared decision-making visits should occur in advance of the LDCT screening. In primary care settings outside of LCS programs, a standardized approach should ensure providers are trained in the identification of patients and conducting SDM visits (Mazzone et al., 2018). Providers should be aware of the counseling requirements and responsibility for conducting SDM visits. Bryne et al. (2019), found that a thorough understanding of factors affecting patient's attitudes toward screening is vital to understanding how to engage patients in SDM. Research has demonstrated an increase in patient knowledge and understanding of LCS with the use of decision aids during SDM visits (Mazzone et al., 2018; Volk & Foxhall, 2015).

Barriers to Shared Decision-making

Shared decision-making discussions are challenging. Wiener et al. (2018) identified several barriers to conducting SDM visits, including competing demands for staff and lack of familiarity with LCS. Competing priorities, poor risk communication skills, and a perception that

patients do not want to engage in SDM have been described in other contexts in addition to LCS (Kandora et al., 2015). One of the more challenging barriers is the perception that patients will not understand or do not want to discuss LCS (Hoffman et al., 2015). Most recently, Huo et al. (2019), identified limited belief in LCS by primary care providers as a key barrier to LCS.

Additional barriers to SDM discussions and ultimately LCS, include a lack of awareness and knowledge of LCS guidelines, including the information required during the SDM discussion (Detterbeck et al., 2013). Barriers to LCS identified by Mishra et al. (2016) include the identification of eligible patients, the management of abnormal results, and the fears and stigma associated with lung cancer. The understanding of these barriers is essential to SDM discussions. Arenberg (2019) reported a lack of understanding of the risks and benefits of LCS inhibit effective discussions with less informed patients, regardless of time constraints.

Lung cancer screening with LDCT is covered under the Affordable Care Act (ACA). Despite CMS and private insurance coverage of LCS with LDCT, cost has been identified as a potential barrier to LCS (Boiselle, 2013). Hoffman et al. (2015) reported that additional costs are associated with follow-up testing to a positive finding and treatment for detected cancers. These costs are not covered as a preventive service under the ACA and are subject to deductibles with the potential to create a financial strain (Hoffman et al., 2015). Toumazis (2019), demonstrated that the cost effectiveness of LCS is associated with the harmful effects of indeterminate findings and should be included during SDM. Additional costs exist for rural patients and include costs related to travel and lost income from time away from work. Fully understanding potential costs is important for patients. Providing this cost information to patients during SDM discussions is important in ensuring the patient has a full understanding of the screening process.

Lung Cancer Screening in Rural Areas

Little research has been conducted on lung cancer screening in rural areas. Although the NLST (2011) established the benefit of LCS with LDCT, the population in the study was not indicative of a rural population. In a review by Jenkins et al. (2018), rural residents were identified as less likely to regularly see a primary care provider, have less access to smoking cessation programs, and experience a worse outcome for cancer diagnosis. A significant concern in rural areas is the decreased access to technology, thus forcing rural residents to travel and incur lost work time for LCS and follow-up (Hoffman et al., 2015).

In addition, Jenkins et al. (2018), identified rural individuals as having worse health outcomes and lower educational levels in comparison to urban individuals. Health literacy significantly impacts the provider's ability to engage in SDM discussions and serves as a barrier to LCS. Simmons et al. (2017) concluded that a provider's lack of knowledge regarding LCS with LDCT affects the willingness of rural providers to recommend LCS.

Malcolm Knowles' Adult Learning Theory

Malcolm Knowles' Adult Learning Theory was selected as the theoretical framework to guide the development and application of education for this project. Knowles' theory is based on the concept of andragogy or helping adults to learn (Merriam, 2018). Introduced in 1973, the model characterizes the differences between "pedagogy (the art of helping children to learn) and andragogy (helping adults to learn)" (Spies, Seale, & Botma, 2015, para. 2). Knowles eventually recognized the continuum of teacher-directed pedagogy to student-directed learning (andragogy) and appropriateness of using both approaches in adult learning (Merriam, 2018). The use of the Adult Learning Theory helps to provide the most appropriate education to promote how adults learn best.

Andragogy attempts to identify how adult learners learn and how to involve them in the learning process. The theory is focused on the understanding that the lecturer does not possess all the knowledge and that students are encouraged to participate in education by using their own experiences (Spies et al., 2015). The following andragogy principles were applied to the development and execution of education for this project.

The first principle is the intrinsic motivation to learn. Adults learn best when they understand why something is important (Merriam, 2018). Motivation to learn comes from both internal and external factors. Adult learners place more priority on internal factors and need to be aware of the reason for education (Spies et al., 2015). Participants in the project were informed of the benefits to using LCS guidelines in their practice by the provision of the education objectives. New knowledge can impact the provider's practice, resulting in increased personal and patient satisfaction.

The next principle is the readiness to learn. For adults, readiness to learn is often influenced by their need to know or do something (Merriam, 2018). Adult learning is problem-centered or life-centered in comparison to subject-matter orientation (Spies et al., 2015). As such, adult learners prefer education presented using real-life situations (Merriam, 2018). The presentation portion of the educational component focused on a case study to illustrate the components and requirements of LCS. In addition, the LCS toolkit provides educational material for additional learning based on the provider's readiness to learn.

The third principle is that adult learners possess prior experience. Adult learners enter learning situations with life experiences that affect how they process information and retain information (Merriam, 2018). The adult learner, feeling responsible for their learning, will resent the lecturer's ideas being forced upon them, rather than acknowledging their prior knowledge

(Spies et al., 2015). Adults learn best when the learning is experiential. Key stakeholders for this project identified LCS knowledge deficits for respective sites. T. Brandner, DNP, FNP-C (personal communication, August 19, 2019), noted that LCS guidelines were not implemented at AMC and identified the need for education regarding LCS guidelines and SDM elements. K. Baloun (person communication, August 23, 2019), identified that providers at Redfield Clinic are not consistently documenting smoking history pack years and the required SDM elements. She reported that recently the LDCT order in the electronic health record (EHR) was revised to include required the CMS elements, making education of LCS guidelines and SDM timely. In addition, the use of the case study during the education session allows providers to draw on past experiences and knowledge to help determine their actions and responses.

Orientation to learning is the fourth principle of andragogy. As previously mentioned, adult learners prefer a problem-solving approach in contrast to a subject-centered approach (Park, Robinson, & Bates, 2016). Adults are more motivated in learning information that helps to solve problems with the ability to apply the new knowledge immediately (Spies et al., 2015). Primary care providers are in a position to decrease lung cancer mortality through identification of patients eligible for LCS and SDM. In addition, through primary care provider's regular interaction with patients, emphasis on continuing the LCS process is possible. Having resources available to ensure providers possess the most current information is necessary for the LCS process and SDM discussions with patients. The LCS education session and toolkit provided up to date information available for immediate use in the provider's practice. In addition to the toolkit binder, an electronic version was provided to the key stakeholders. The toolkit provided internet links for current resources.

The fifth principle is self-directed learning. Adult learners have individual self-concepts and respond to education led by self-directedness (Spies et al., 2015). Despite having learning needs that are influenced by societal and social roles, adults have progressed from a dependent personality to an independent, more self-directing individual (Merriam, 2018). Any opportunity to control or provide input into the education enhances the learning experience for the adult (Park et al., 2016). Key stakeholders from both sites were contacted during the development of the education session and toolkit to ensure information was relevant and needed at the respective sites. The toolkits, both binder and electronic version, included the PowerPoint presentation for self-directed learning or review of presentation.

The final principle is the need to know. Adult learning is best achieved when they understand why they need the information prior to participating in the education session (Spies et al., 2015). Objectives for the LCS education session were provided to the participants prior to the education session, allowing for the participants to understand why the information is essential to them and helped to establish personal value for the education. The importance of understanding LCS guidelines and SDM was highlighted at the start of the education session, emphasized throughout the session, and reviewed at the conclusion to improve the understanding of the project's impact on specific learning goals. During the education session, input from participants reinforced the value in the education sessions.

CHAPTER THREE. METHODS

Project Design

The design of this project is practice improvement, with implementation of an evidence-based intervention in two healthcare settings, pre- and post-tests, and chart audit. The purposes of this project and specific objectives are included in Chapter One. Using the best evidence available, the project translates evidence into clinical practice.

Project Implementation Plan

IOWA Model

Evidence-based practice (EBP) combines clinician expertise, patient preferences, and values with the best evidence from well-designed research as a guide to problem-solving (Dang et al., 2015). EBP models are used to assist healthcare providers in the integration of best evidence into clinical practice. For this project, the Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care (Appendix C) was used to facilitate the implementation of the USPSTF's LCS guideline at AMC and Redfield Clinic. The Iowa Model, consisting of several problem-solving steps and feedback loops, is widely used and validated as a guide for EBP projects (Iowa Model Collaborative, 2017). Permission to use the model was obtained from the University of Iowa Hospitals and Clinics (Appendix D).

Identification of a problem-focused or knowledge-focused trigger is the first step in the Iowa Model (Iowa Model Collaborative, 2017). "Triggers" arise from questions surrounding current practice or acquisition of new knowledge, such as a guideline, leading to opportunities for practice change and improved patient outcomes (Dang et al., 2015). Since 2013 when the ACS and USPSTF released LCS guidelines, implementation of the guidelines has been slow. The 2015 National Health Interview Survey noted that only 5% of eligible individuals eligible

had been screened for lung cancer (Huo et al., 2017). Challenges in the implementation of LCS with LDCT identified in a recent VHA study included difficulty in identifying patients eligible for screening (Kinsinger et al., 2017). Based on the USPSTF grade B recommendation and CMS support for annual screening, key stakeholders at the clinics verified the need to implement LCS guidelines. Education regarding LCS guidelines and SDM was requested as part of the implementation strategy.

The next step is to determine if the change is a priority for the organization. Implementation of LCS guidelines in the clinics needed to be considered an organizational priority for the success of the project (Brown, 2014). Key stakeholders expressed support and interest in LCS education and implementing LCS guidelines in the clinics (T. Brandner, personal communication, August 19, 2019; K. Baloun, personal communication, August 23, 2019). Once the change is deemed a priority, the next step is to form a team of stakeholders to help develop, evaluate, and implement the practice change (Brown, 2014).

Stakeholders for this project were numerous. Lead team members consisted of the co-investigator; advance practice nurse and unit manager at AMC; and unit manager at Redfield Clinic. Additional team members at AMC included advance practice nurses, and clinic support staff at AMC. Additional team members at Redfield Clinic included physicians, advance practice nurse, physician assistants and clinic support staff. Although the additional team members were not as active in the development of the project, their input and cooperation were imperative for the evaluation and implementation of the practice change. My role as the co-investigator was to provide education and facilitate implementation and use of the LCS guideline. The dissertation committee for the project included Dr. Kelly Buettner-Schmidt as chair from the School of

Nursing, Dr. Dean Gross from the School of Nursing, Dr. Christopher Whitsel as North Dakota State University graduate appointee, and Dr. Tara Brander, nurse practitioner from AMC.

The next steps are to gather, critique, and synthesize relevant research related to the proposed practice change (Iowa Model Collaborative, 2017), this has been accomplished through the review of literature provided in this dissertation. Through the project proposal process, the literature review and from key stakeholders, it was determined that enough evidence for a practice change existed.

The next step is to design and pilot the practice change. This project was modeled after a similar project that introduced and educational toolkit for lung cancer screening (Cloonan, 2017). Similar to Cloonan (2017), this project included an education session and toolkit and evaluated with a pre-, immediate post-, and two-month post-education evaluation. The project completed by Cloonan (2017), will be considered the pilot. Following the project approval by the Dissertation Committee and subsequent IRB approval, this co-investigator developed and implemented the practice change intervention at both clinic sites.

Following implementation, continued evaluation is needed to identify deviations and reinforce the change (Brown, 2014). One month following the implementation of the educational intervention, key stakeholders at both clinics were contacted to identify any additional educational needs related to LCS guidelines. Additional education and resources requested by the clinics were provided by the co-investigator.

Finally, dissemination of the results is vital for professional learning and the generation of additional practice questions or triggers (Dang et al., 2015). Dissemination of results occurred through this dissertation and executive summary (Appendix E). The executive summary was

provided to the stakeholders via an electronic email. In addition, the author will develop a three-minute thesis video and present a final poster at North Dakota State University on April 1, 2020.

Setting

The setting for this project consisted of two rural clinics. The clinics were selected after the co-investigator completed clinical rotations in both locations and observed inconsistent or lack of LCS guidelines use at the clinics. The first clinic, AMC, is located in southcentral ND. In 2017, the population of Ashley's was 689 with a median age of 66.2 years (City-data.com, n.d.-a). The education session for the project was offered to the three nurse practitioners and six supporting clinic staff at AMC. Supporting clinic staff included a clinic manager, registration staff and nursing staff.

The second clinic, Redfield Clinic, is located in northcentral SD. In 2017, the population for Redfield was 2,295 with a median age of 44.9 years (City-data.com, n.d.-b). The education session for the project were offered to the three physicians, one nurse practitioner, three physician assistants and 25 supporting clinic staff. Supporting clinic staff included the Chief Executive Officer, medical records staff, a clinic manager, nursing staff, an administrative assistant and pharmacy professionals and staff.

Participants

Participants of the practice improvement project consisted of a purposive sample made up of providers from AMC and Redfield Clinic. Eligible providers included all providers employed at AMC and Redfield. In addition to providers at the clinics, the education session was offered to the supporting clinic staff. Evaluation surveys measuring knowledge and confidence were administered only to the primary care providers in attendance. Lung cancer screening toolkits were distributed to the primary care providers and clinics during the education session.

NDSU IRB approval (Appendix F) and institutional approval (Appendix G) was obtained prior to the project implementation. The surveys included a consent statement explaining that participation implied informed consent, participation was voluntary, and the decision to stop was the right of the participant. Risks to the participants included time to complete the survey and possible mild distress in completion of knowledge questions. The benefit of the educational intervention was available to all eight providers and clinical support staff in attendance at the education session. Benefits of the module included knowledge of LCS guidelines, CMS requirements for LCS and SDM. In addition to the education session, the LCS toolkit provided resources to assist in identifying eligible patients, initiating SDM discussions with patients, decision aids, and ensuring the required elements are met.

Project Intervention

The first objective for this project consisted of the development and implementation of an educational intervention. This project was adapted from a project that created an educational LCS toolkit and decision aid (Cloonan, 2017). The educational intervention consisted of an education session and LCS toolkit regarding LCS and CMS required SDM discussion elements. The educational intervention was developed based on the review of literature and with the input and approval of the dissertation committee. The education session consisted of a PowerPoint presentation concentrating on the knowledge of LCS and SDM using a case study developed by the co-investigator to enhance provider learning. Specifically, the education session focused on lung cancer and screening, benefits and harms of LCS, LCS guidelines, CMS requirements, elements of SDM discussions, and review of the LCS toolkit (Appendix H). The information presented was reinforced by clinic administration commenting that previous claims have been denied for lack of documentation. This information was well received by the providers.

The LCS toolkit was developed based on the review of various organizations' recommendations, including the Agency for Healthcare Research and Quality, ACS, American College of Radiology, CDC, CMS, Lung Cancer Alliance, and USPSTF, and with input and approval of the dissertation committee. In addition to providing resources for patient education; information in the LCS toolkit included websites, decision aids, and checklists to help providers meet CMS requirements (see Appendix I). Three LCS toolkits were distributed to each of the clinics following the education session. In addition, the key stakeholders at each clinic were provided electronic copies of the toolkit. Each clinic was contacted one month following the education session and additional copies of the pack year calculator and decision aid were provided as requested.

Project Evaluation

To evaluate the first objective, two evaluations on paper, one at the conclusion of the education session and one two-months post-education session were collected. The LCS education session evaluation consisted of four Likert-scale questions measuring the content of the session as it relates to the providers educational needs and benefit to practice. Two additional questions were available for providers to add comments and suggestions for additional information. The LCS toolkit evaluation, collected two-months post education session, consisted of three Likert-scale questions measuring the content of the toolkit as it relates to the providers educational needs and benefit to practice. Two additional questions were available for providers to add comments and suggestions for additional information.

The second objective for this project was to determine the impact of the project intervention through the evaluation. The intervention evaluation consisted of participant surveys

and retrospective chart audits. IRB approval was received on October 15, 2019, prior to any data collection.

Provider urveys

Data collected through provider surveys were used to evaluate Objectives 1, 2a, and 2b. Project participants were asked to complete three paper surveys, one pre-education session, one immediate post-education session, and the third, two-months following the educational intervention. The survey was adapted with permission from a study by Lewis et al. (2019) regarding provider knowledge of LCS. The survey assessed guideline knowledge, patient eligibility, and SDM. The study by Lewis et al. (2019) defined high knowledge of LCS guidelines as correctly identifying the three major criteria of LCS: initial age, minimum smoking exposure, and smoking status, while low knowledge was defined as not identifying these three criteria. In addition, knowledge was converted into a continuous variable with zero correct items indicating the least knowledge and six correct the most knowledge. Lewis et al.'s survey was pilot tested with physicians, including cognitive interviews prior to use. Formal psychometric testing was not completed. See Appendix J for permission to use Lewis et al.'s survey.

All three surveys evaluated provider knowledge and confidence in relation to LCS guidelines and SDM. The pre- and two post-education surveys included identical questions regarding knowledge of LCS guidelines and the related CMS requirements for LCS and SDM discussions. In addition, the pre- and two post-education surveys included identical questions regarding confidence in the initiation of SDM discussions. See Appendix K for the questions included in the survey.

Prior to the education session, the paper pre-education survey and attached consent were distributed to the providers in attendance. Following the education session, the immediate post-

education survey and LCS education evaluation were distributed to participants of the education session to evaluate the co-investigators presentation (Appendix L). All surveys (pre-; immediate post-; and evaluation) were collected in a manila envelope at the completion of the education session. Due to the small sample size and to ensure anonymity the paper surveys from both sites were collected in the same manila envelope and resulted at the completion of the second education session. Two months after the education session, on January 20, 2020 and January 24, 2020, the third survey (two-month post-education survey) was distributed to participants that completed the pre-, and immediate post-education surveys by the co-investigator. The manila envelope for collecting surveys was placed on the clinic manager's desk at Redfield. The providers upon completion, placed the surveys in the envelope and this co-investigator collected the envelope at the end of the day (January 20, 2020). The manila envelope for collecting surveys was placed on a desk next to the co-investigator during the chart audit on January 24, 2020 at AMC. The providers upon completion, placed the surveys in the envelope.

The LCS toolkit evaluation was distributed to the participants that completed the pre-, and immediate post-education surveys at the same time as the two-month post-education survey (Appendix M). The surveys and evaluations from both clinic sites were collected in the same manila envelope, stored in a locked drawer at the co-investigator's residence and resulted together. After the completion of the results, the surveys were shredded.

Retrospective chart audit

The retrospective chart audit included EHR data collected prior to the education session and for the immediate two months following the education session. Specifically, the collected EHR data evaluated Objectives 2c, 2d, and 2e, which included assessing for an increased number of patients identified meeting eligibility requirements for LCS (patients age 55 to 77 years

greater than or equal to 30 pack-year, current or former smokers with documented smoking cessation within the past 15 years); increased number of documented SDM discussions between primary care providers and patients at high-risk for lung cancer; and increased number of referrals for LDCT or to specialists for LCS in eligible patients. An excel spreadsheet was used to collect the data (Appendix N).

Data Analysis

Data analysis of the primary care providers' pre-, immediate post-, and two-month post-education surveys and retrospective chart audit were analyzed electronically using Qualtrics, Excel, and SPSS. The quantitative data analysis consisted of simple statistical tests with mean scores for Likert scale responses on the surveys. The remainder of the data on the surveys and retrospective chart audit were analyzed with numbers, percentages, frequencies, and statistical tests. A statistician from NDSU was consulted for assistance with the data analysis and descriptive statistics.

CHAPTER FOUR. RESULTS[1]

Presentation of Results

Education sessions were presented during the Redfield Clinic medical staff meeting on November 20, 2019 and the AMC staff meeting on November 27, 2019. The education sessions were open to all clinic staff. Data were collected using pre-, immediate post-, and two-month post-education surveys, and retrospective chart audit.

The co-investigator was granted access to the EHR on January 21, January 24, and January 28, 2020 for the purpose of data collection. No patient identifiers were collected, and the clinic provided reports remained at the clinic. The electronic spreadsheets were password protected on the co-investigator's laptop.

Demographics

Demographic data were collected on the pre-, immediate post-, and two-month post-education survey. The total number of participants for the education sessions was 28 between the two sites. Eight primary care providers attended the education sessions and were invited to complete the surveys (Table 2).

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[1] The material in this chapter was co-authored by Teresa Formo and Dr. Kelly Buettner-Schmidt. Teresa Formo had primary responsibility for collecting samples in the field and for interviewing users of the test system. Teresa Formo was the primary developer of the conclusions that are advanced here. Teresa Formo also drafted and revised all versions of this chapter. Dr. Kelly Buettner-Schmidt served as proofreader and checked the math in the statistical analysis conducted by Teresa Formo.

Table 2

Demographics of Survey Responders

	Pre- & Immediate Post-Ed		Two-month Post-Ed	
	n = 5	**63%**	**n = 3**	**60%**
Profession				
Physician	0			
Physician Assistant	2	40	1	33
Nurse Practitioner	3	60	2	67
Years in Clinical Practice				
0 - 3 years	0		0	
4 - 6 years	3	60	2	67
7 - 9 years	1	20	0	
10 - 12 years	0		0	
Greater than 12 years	1	20	1	33

Ed. = education

Of the eight primary care providers in attendance, five (63%) completed the pre-, and immediate post-education surveys. The majority of the participants (n = 3) were nurse practitioners, the remaining participants (n = 2) were physician assistants. Of the five providers completing the pre- and immediate post-education surveys, three (60%) completed the two-month post-education survey. The majority completing the two-month survey were nurse practitioners (n = 2). The level of experience ranged from 4 to greater than 12 years.

Objective One

The first objective was to develop and implement an educational intervention consisting of LCS education session and LCS toolkit, regarding LCS and the CMS required SDM discussion elements to improve the use of published LCS guidelines by providers. See Table 3 for activities conducted in relation to development and implementation of the intervention.

Table 3

Objective One Activities, and Evaluation

	Objective	Activities	Evaluation
1	Develop and implement an educational intervention consisting of an education session and toolkit regarding lung cancer screening and the required shared decision-making discussion elements to improve access to and use of published lung cancer screening evidenced based practice by providers.	• Conducted a literature review • Developed education session using PowerPoint presentation. • Developed LCS toolkit with educational resources. • Implemented LCS educational intervention consisting of PowerPoint and LCS toolkit to providers at two rural clinics on 11/20/2019 and 11/27/2019.	• Collected provider completed LCS education session evaluation on 11/20/2019 and 11/27/2019 (questions 1 - 6). • Collected provider completed LCS toolkit evaluation on 01/20/2020 and 01/24/2020 (questions 1 - 5).

LCS = lung cancer screening.

The LCS education evaluation was collected immediately following the education session at both clinics. A total of five evaluations were returned (Table 4).

Table 4

Survey Results LCS Education Evaluation

	n = 5	%
Education presentation objectives were met		
Strongly agree	5	100
Somewhat agree	0	
Neutral	0	
Somewhat disagree	0	
Strongly disagree	0	
Content met educational needs		
Strongly agree	5	100
Somewhat agree	0	
Neutral	0	
Somewhat disagree	0	
Strongly disagree	0	
Content beneficial to practice		
Strongly agree	4	80
Somewhat agree	0	
Neutral	1	20
Somewhat disagree	0	
Strongly disagree	0	
Content easy to understand and free of bias		
Strongly agree	5	100
Somewhat agree	0	
Neutral	0	
Somewhat disagree	0	
Strongly disagree	0	

LCS = lung cancer screening.

All the participants (100%) reported that the education session met the stated objectives and met the educational needs of the provider, having indicated “strongly agree” on the evaluation. Of the participants, 80% selected “strongly agree” that the content was beneficial to their practice. The remaining participant (20%) selected “neutral”. All the participants indicated that the education was easy to understand and free of bias, by selecting “strongly agree”. Qualitative data included the comments “very informative”, “kept my attention, presented well”, and “nice job”.

The LCS toolkit evaluation was collected two-months after the education session at both sites. Three toolkit evaluations were completed and returned (Table 5).

Table 5

Survey Results LCS Toolkit Evaluation

	n = 3	**%**
Content met educational needs		
Strongly agree	2	67
Somewhat agree	1	33
Neutral	0	
Somewhat disagree	0	
Strongly disagree	0	
Content beneficial to practice		
Strongly agree	2	67
Somewhat agree	1	33
Neutral	0	
Somewhat disagree	0	
Strongly disagree	0	
Content easy to understand and free of bias		
Strongly agree	3	100
Somewhat agree	0	
Neutral	0	
Somewhat disagree	0	
Strongly disagree	0	

LCS = lung cancer screening.

The majority of the participants (67%) selected “strongly agree” that the content of the toolkit met their educational needs and that the toolkit was beneficial to their practice. The remaining participant (33%) selected “somewhat agree”. All the participants (100%) indicated that they “strongly agree” that the content was easy to understand and free from bias. Comments included “could use a patient checklist sheet to assess qualifications”.

Objective Two

The second objective for the project was to determine the impact of the intervention and was divided into five sub-objectives. As previously discussed, data for this objective were collected using pre-, immediate post-, and two-month post-education surveys and retrospective chart audit. See Table 6 for objective two activities and evaluation.

Table 6

Objective Two Activities and Evaluation

	Objectives	**Activities**	**Evaluation**
2a	Assess for an increase in knowledge of rural primary care providers regarding lung cancer screening guidelines, including shared decision-making discussions.	• Education session for providers regarding LCS with LDCT and LCS guidelines conducted on 11/20/2019 and 11/27/2019. • Each clinic received three LCS toolkit with educational resources for providers and staff on 11/20/2019 and 11/27/2019.	• Collected provider completed pre- and immediate post-education surveys on 11/20/2019 and 11/27/2019; and two-month post-education surveys on 01/20/2020 and 01/24/2020 to evaluate knowledge regarding LCS guidelines (questions 4 - 9). • Collected provider completed pre- and immediate post-education surveys on 11/20/2019 and 11/27/2019; and two-month post-education surveys on 01/20/2020 and 01/24/2020 to evaluate knowledge regarding CMS requirements for LCS and SDM visits (questions 2 - 3).

Table 6. *Objective 2 Activities and Evaluation* (continued)

	Objectives	Activities	Evaluation
2b	Assess for an increase in the confidence of rural primary care providers in initiating shared decision-making discussions with eligible patients at high-risk for lung cancer.	• Education session for providers regarding the identification of patients at high-risk for lung cancer and the importance of SDM discussions, including required elements with patients at high risk for lung cancer conducted on 11/20/2019 and 11/27/2019.	• Collected provider completed pre- and immediate post-education survey on 11/20/2019 and 11/27/2019; and two-month post-education surveys on 01/20/2020 and 01/24/2020 to evaluate perceived confidence in initiating SDM (question 1).
2c	Assess for an increase in the number of patients identified at high-risk for lung cancer and eligible for lung cancer screening by rural primary care providers.	• Education session for providers regarding the identification of patients at high-risk for lung cancer and eligible for screening conducted on 11/20/2019 and 11/27/2019.	• Retrospective Chart Audit: Collected EHR data for the number of patients identified as eligible for LCS (patients age 55 to 77 years, greater than or equal to 30 pack-year smoking history, current or former smokers with smoking cessation within the past 15 years) at both clinics. Redfield: Data collected on 01/20/2020 and 01/28/2020 for the time periods of 06/01/2019 through 07/31/2019 and 11/21/2019 through 01/20/2020. AMC: Data collected on 01/24/2020 for the time periods of 06/01/2019 through 07/31/2019 and 11/27/2019 through 01/24/2020.
2d	Assess for an increase in the number of shared decision-making discussions, inclusive of all required elements, initiated between rural primary care providers and patients at high-risk for lung cancer.	• Education session for providers regarding the importance of an SDM discussions, including required elements with patients at high risk for lung cancer conducted on 11/20/2019 and 11/27/2019.	• Retrospective Chart Audit: Collected EHR data for the number of documented SDM discussions, inclusive of all required elements, between rural primary care providers and patients at high-risk for lung cancer at both clinics. Redfield: Data collected on 01/20/2020 and 01/28/2020 for the time periods of 06/01/2019 through 07/31/2019 and 11/21/2019 through 01/20/2020. AMC: Data collected on 01/24/2020 for the time periods of 06/01/2019 through 07/31/2019 and 11/27/2019 through 01/24/2020.

Table 6. *Objective 2 Activities and Evaluation* (continued)

	Objectives	Activities	Evaluation
2e	Assess for an increase in the number of referrals for LDCT or to specialists for lung cancer screening in eligible high-risk patients by rural primary care providers.	• Education session for providers regarding the importance of LCS guidelines and LDCT or specialist referral of eligible patients at high-risk for lung cancer conducted on 11/20/2019 and 11/27/2019.	• Retrospective Chart Audit: Collected EHR data for the number of documented LDCT or specialist referral of eligible patients at high-risk for lung cancer at both clinics. Redfield: Data collected on 01/20/2020 and 01/28/2020 for the time periods of 06/01/2019 through 07/31/2019 and 11/21/2019 through 01/20/2020. AMC: Data collected on 01/24/2020 for the time periods of 06/01/2019 through 07/31/2019 and 11/27/2019 through 01/24/2020.

LCS = lung cancer screening. LDCT = low-dose computed tomography. CMS = Centers for Medicare and Medicaid Services. SDM = shared decision-making. EHR = electronic health record. AMC = Ashley Medical Center.

Objective 2a

Objective 2a assessed for an increase in the knowledge of rural primary care providers regarding LCS guidelines and the related CMS requirements for LCS and SDM discussions.

Knowledge of LCS guidelines. Knowledge of USPSTF guidelines and CMS criteria for LCS was assessed through six multiple-choice items adapted from Lewis et al. (2019) survey. Knowledge was divided into high LCS and low LCS knowledge and as a continuous variable, measuring most LCS knowledge to least LCS knowledge. The following items were assessed:

- Q4: Age patients are eligible to begin LCS with LDCT (correct answer: 55)
- Q5: Age patients are no longer eligible for LCS with LDCT (correct answer: either 77 or 80)
- Q6: Minimum smoking exposure in pack years (correct answer: 30 pack-years)
- Q7: Smoking status (correct answer: current and former smokers)
- Q8: LDCT screening for patients not surgical candidates (correct answer: no)

- Q9: LDCT screening frequency (correct answer: 1 year)

Refer to Table 7 for Survey Results of LCS Knowledge.

Table 7

Survey Results of LCS Knowledge

	Pre-Ed.		Immediate Post-Ed.		Two-month Post-Ed.	
	n = 5	**%**	**n = 5**	**%**	**n = 3**	**%**
Q4: Age (in years) patients are eligible to begin LCS with LDCT						
30	0		0		0	
35	0		0		0	
40	0		0		0	
45	0		0		0	
50	3	60	0		0	
55*	1	20	5	100	3	100
60	1	20	0		0	
65	0		0		0	
Other	0		0		0	
Don’t know	0		0		0	
Q5: Age (in years) patients are no longer eligible for LCS with LDCT						
65	0		0		0	
70	0		0		0	
75	0		0		0	
76	0		0		0	
77*	2	40	4	80	1	33
78	0		0		2	67
79	0		0		0	
80*	2	40	1	20	0	
81	1	20	0		0	
85	0		0		0	
Other	0		0		0	
No Upper Age	0		0		0	
Q6: Minimum smoking exposure						
10 pack years	2	40	0		0	
20 pack years	1	20	0		0	
30 pack years*	2	40	5	100	5	100
40 pack years	0		0		0	
50 pack years	0		0		0	
Other	0		0		0	
Don’t know	0		0		0	

Table 7. *Survey Results of LCS Knowledge* (continued)

	Pre-Ed.		Immediate Post-Ed.		Two-month Post-Ed.	
	n = 5	**%**	**n = 5**	**%**	**n = 3**	**%**
Q7: Smoking Status						
Current smokers only	0		0		0	
Former smokers only	0		0		0	
Both current and former smokers*	5	100	5	100	5	100
Don't know	0		0		0	
Q8: LCS with LDCT for patients not surgical candidates						
Yes	3	60	0		1	33
No*	2	40	5	100	2	67
Don't know	0		0		0	
Q9: Recommended frequency for LCS with LDCT						
1 year*	2	40	4	80	2	67
2 years	2	40	1	20	0	
4 years	0		0		0	
5 years	0		0		0	
10 years	1	20	0		1	33
Other	0		0		0	
Don't know	0		0		0	

*correct answer(s). LCS = lung cancer screening. Ed. = education. LDCT = low-dose computed tomography. Pack years = number of packs/day x years smoked. 1 pack = 20 cigarettes.

High versus low knowledge. High LCS guideline knowledge was defined as the correctly identifying the three major criteria associated with eligible LCS candidates: initial age of LCS eligibility, minimum smoking exposure and smoking status (questions four, six and seven). Low LCS knowledge was defined as not correctly identifying the three major criteria. See Table 8 for the results.

Table 8

Survey Results of High Knowledge Versus Low Knowledge

	Pre-Ed.		Immediate Post-Ed.		Two-month Post-Ed.	
	n =5	**%**	**n = 5**	**%**	**n = 3**	**%**
High Knowledge	1	20	5	100	3	100
Low Knowledge	4	80	0		0	

Ed. = education

Prior to the education session, only 20% (n = 1) met the definition for high knowledge of LCS, with the majority, 80% (n = 4), defined as having low knowledge of LCS. All the participants (100%) were defined as having high knowledge of LCS on the immediate post- and two-month post-education surveys.

Most versus least knowledge. Knowledge of LCS guidelines was redefined as a continuous variable based on correct answers to all six items, with the least knowledge having zero correct and the most knowledge having all six items correct. See Table 9 for results.

Table 9

Survey Results of Most Knowledge to Least Knowledge

	Pre-Ed.		Immediate Post-Ed.		Two-month Post-Ed.	
# of Correct Items	**n =5**	**%**	**n = 5**	**%**	**n = 3**	**%**
2	2	40	0		0	
3	1	20	0		1	33
4	2	40	0		0	
5	0		1	20	1	33
6	0		4	80	1	33

Ed. = education. Most knowledge is associated with most correct items.

Prior to the education session, all the participants answered four or less items correctly. Immediately post-education, the majority, 80% (n = 4), answered six of six items correctly. Two-months post-education 67% (n = 2) of participants answered five or six of six items and 33% (n = 1) of participants answered three items correctly.

Knowledge of CMS requirements. Knowledge related to CMS requirements for LCS and SDM was assessed through questions two and three (Table 10).

Table 10

Survey Results of Knowledge of CMS Requirements for LCS and SDM

	Pre-Ed.		Immediate Post-Ed.		Two-month Post-Ed.	
	n = 5	**%**	**n = 5**	**%**	**n = 3**	**%**
Q2: Elements required for CMS reimbursement for SDM (multiple answers possible)						
Benefits of screening*	4	80	5	100	3	100
Harms of screening*	1	20	5	100	3	100
False positives*	0		5	100	2	67
Follow-up testing*	2	40	5	100	2	67
Overdiagnosis*	0		5	100	2	67
Total radiation exposure*	2	40	5	100	2	67
Adherence to annual screening*	2	40	5	100	3	100
Impact of comorbidities*	1	20	5	100	2	67
Ability/willingness to undergo diagnosis and treatment*	1	20	5	100	3	100
Maintaining cigarette smoking abstinence if former smoker*	2	40	5	100	3	100
Importance of smoking cessation if current smoker*	2	40	5	100	3	100
Don't know	1	20	0		0	
Other	0		0		0	
Q3: Required SDM documented by CMS (multiple answers possible)						
DOB / Age*	4	80	5	100	3	100
Pack-years smoking history*	5	100	5	100	3	100
Smoking status*	5	100	5	100	3	100
Number of years since quitting*	5	100	5	100	3	100
Statement no lung cancer signs or symptoms*	1	20	5	100	2	67
Statement no lung cancer family history	1	20	0		0	
Other	0		0		0	
Don't know	0		0		0	

*correct answers. CMS = Centers for Medicare and Medicaid Services. Ed. = education. SDM = shared decision-making. Pack years = number of packs/day x years smoked. 1 pack = 20 cigarettes.

For question two, participants were asked to select all applicable SDM elements required by CMS. Of the 13 items, 11 responses were correct. Incorrect responses included “other” and “don’t know” (See Table 11).

Table 11

Survey Results of the Number of Correctly Identified SDM Elements Required by CMS

	Pre-Ed.		Immediate Post-Ed.		Two-month Post-Ed.	
# Correct Items	**n =5**	**%**	**n = 5**	**%**	**n = 3**	**%**
11	0		5	100	2	67
10	0		0		0	
9	0		0		0	
8	0		0		0	
7	0		0		0	
6	2	40	0		1	33
5	0		0		0	
4	1	20	0		0	
3	0		0		0	
2	0		0		0	
1	1	20	0		0	
0	1	20	0		0	

CMS = Centers for Medicaid and Medicare Services. SDM = shared decision-making. Ed. = education.

Prior to the education, no participants correctly selected all eleven elements, 40% (n = 2) of participants correctly selected six of the eleven elements, 20% (n = 1) correctly selected four elements, 20% (n = 1) correctly selected one element and 20% (n = 1) did not select any correct elements. Immediate post-education found 100% (n = 5) of participants correctly selected all eleven elements. Two-months post-education, 67% (n = 2) of participants correctly selected all eleven elements with the remaining participants, 33% (n = 1), correctly selecting six of eleven elements.

For question three, participants were asked to select all the statements needed for SDM documentation for CMS payment of LCS with LDCT. Of the eight items, five of the responses

were correct statements. Incorrect responses included “statement that the patient does not have a family history of lung cancer”, “other”, and “don’t know” (Table 12).

Table 12

Survey Results for Knowledge of SDM Documentation for LCS with LDCT

	Pre-Ed.		Immediate Post-Ed.		Two-month Post-Ed.	
# Correct Items	**n =5**	**%**	**n = 5**	**%**	**n = 3**	**%**
5	1	20	5	100	2	67
4	3	60	0		1	33
3	1	20	0		0	
2	0		0		0	
1	0		0		0	
0	0		0		0	

SDM = shared decision-making. Ed. = education.

Prior to education, the majority of the participants (60%) correctly selected four of the five statements with 20% of participants correctly selecting all five correct statements. Immediate post-education found 100% (n = 5) of participants correctly selecting all five statements. Two-months post-education, the majority of participants, 67% (n = 2), correctly selected all five statements with the remaining participants correctly selecting four of five statements.

Objective 2b

Objective 2b assessed for an increase in the confidence of rural primary care providers initiating share decision-making discussions (question one). Table 13 presents the results.

Table 13

Survey Results of Provider Confidence

	Pre-Ed.		Immediate Post-Ed.		Two-month Post-Ed.	
	n = 5	**%**	**n = 5**	**%**	**n = 3**	**%**
Q1: Confidence in initiating SDM discussion						
Very confident	0		1	20	0	
Somewhat confident	4	80	4	80	3	100
Not at all confident	1	20	0		0	

Ed. = education. SDM = shared decision-making.

Prior to the education session, the majority of the participants, 80% (n = 4), reported being somewhat confident in initiating SDM discussions, with confidence increasing immediately post-education, and then declining somewhat two months post-education. However, from pre-education to two months post-education, confidence did increase.

Responses to question one was ranked with 1 = "not at all confident", 2 = "somewhat confident", and 3 = "very confident". The mean score of the surveys were calculated and a paired samples t-test was used to compare the mean pre-education confidence level to the immediate post-education confidence level. The mean score of the pre-education survey (n = 5) was 1.80 (sd = .45) and the mean score of the immediate post-education survey (n=5) was 2.20 (sd = .45). No significant difference from pre- to immediate post-education was found ($t(4) = -1.633$, $p>.05$). Due to lower response, the two-month post-education confidence level was not included.

Objective 2c

Objective 2c assessed for an increase number of patients identified at high-risk for lung cancer and eligible for LCS by rural primary care providers. Data for this objective were collected by retrospective chart audit previously discussed. Eligibility for LCS requires documentation of age (55 - 77), smoking status, quit date, and pack years.

Redfield. Redfield Clinic provided the co-investigator with a report of patients seen in the clinic during the pre-education period, June 2019 through July 2019, and the post-education period, November 20, 2019 through January 20, 2019. The report was filtered for ages 55 through 80 years and included smoking status of current, former, or unknown. A total of 249 patient records (age 55 - 77) were reviewed for the pre-education period and 236 patient records (age 55 - 77) were reviewed for the post-education period (See Table 14).

Table 14

Results of Eligibility Documentation – Redfield

			Quit Date Documented		Quit Date ≤ 15 Years		Pack Years Documented		Pack Years ≥ 30 Years	
Smoking Status	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Pre-Education (n = 249)							**14**	**6**	**8**	**3**
Former smokers	167	67	65	39	28	43	10	6	5	50
Current smokers	81	33					4	5	3	75
Not documented	1	<1								
Post-Education (n = 236)							**40**	**17**	**26**	**11**
Former smokers	157	67	66	42	31	47	18	11	13	72
Current smokers	77	33					22	29	13	59
Not documented	2	<1								

LCS = lung cancer screening. Pack years = number of packs/day x years smoked. 1 pack = 20 cigarettes.

Patient age was documented on all the records. Of the reviewed records two-thirds were former smokers and one-third were current smokers, with less than 1% not having smoking status documented. Prior to the education pack-years was documented in only 6% of the records with an increase to 17% post-education. Quit date was documented in less than half of former smoker records.

To determine LCS eligibility, documentation for patients age 55 – 77 was reviewed for a quit date equal or less than 15 years for former smokers, and for pack years equal or greater than 30 years for current and former smokers (Table 15).

Table 15

Results of LCS Eligibility – Redfield

		LCS Eligible		Not Eligible		Unable to Determine	
	n	**n**	**%**	**n**	**%**	**n**	**%**
Pre-Education	**249**	**4**	**2***	**39**	**16***	**205**	**82***
Former Smoker	167	1	<1	38	23	128	77
Current Smoker	81	3	4*	1	1	77	95
Not documented	1					1	100
Post-Education	**236**	**17**	**7***	**47**	**20***	**172**	**73***
Former smoker	157	4	3	38	24	115	73
Current Smoker	77	13	17*	9	12	55	71
Not documented	2					2	100

LCS = lung cancer screening.
* Percentages differ significantly for eligible for LCS, current smokers eligible for LCS, and unable to determine, $p < .05$

Based upon the pre-education documentation for former smokers, less than < 1% (n = 1) were eligible for LCS. Of the pre-education records reviewed for current smokers 4% (n = 3) were eligible for LCS. Post-education documentation found 3% (n = 4) of former smokers and 17% (n = 13) of current smokers eligible for LCS. Of note is the high percentage of patients lacking documentation to determine eligibility. For the records reviewed, 82% (n = 205) of pre-education and 73% (n = 172) of post-education, the documentation was insufficient to determine LCS eligibility.

A two-sample t-test was performed to determine whether there was a significant difference between the pre- and post-education percentages for patients in which LCS eligibility was unable to be determined, between the pre- and post-education percentages for patients eligible for LCS, and between the pre- and post-education percentages for current smokers eligible for LCS. The decrease in the percentage of patients (pre- to post-education) in which LCS was unable to be determined, was significant at the 0.5 alpha level $t(483) = 2.377$, $p = .0178$. Likewise, the increase in the percentage of patients found to be eligible for LCS was

significant at the 0.5 alpha level $t(483) = 2.674$, $p = .0078$ and the increase in the percentage of current smokers found to be eligible for LCS was significant at the 0.5 alpha level $t(156) = 2.683$, $p = .0081$.

AMC. AMC provided the co-investigator with a report of patients seen in the clinic during the pre-education period, June 2019 through July 2019, and the post-intervention period, November 27, 2019 through January 24, 2019. The report was filtered for ages 55 through 80 years. A total of 174 patient records (age 55 - 77) were reviewed for the pre-education period and 172 patient records (age 55 - 77) were reviewed for the post-education period. Patient age was documented on all the records. Of the reviewed records, 57% (n = 100) of the pre-education and 55% (n = 95) of the post-education records, were excluded for status of "never smoker". Of the remaining records, nearly two-thirds were former smokers and just over one-third were current smokers or did not have a smoking status documented (Table 16).

Table 16

Results of Eligibility Documentation – AMC

			Quit Date Documented		**Quit Date ≤ 15 Years**		**Pack Years Documented**		**Pack Years ≥ 30 Years**	
Smoking Status	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Pre-Education (n = 75)							**20**	**27**	**6**	**8**
Former smokers	48	64	4	8	0		12	25	2	17
Current smokers	14	19					8	57	4	50
Not documented	12	16								
Post-Education (n = 77)							**24**	**31**	**11**	**14**
Former smokers	53	68	10	19	1	2	14	26	4	29
Current smokers	16	21					10	63	7	70
Not documented	8	10								

LCS = lung cancer screening. AMC = Ashley Medical Center. Pack years = number of packs/day x years smoked. 1 pack = 20 cigarettes.

An increase of 6% in smoking status documentation was found from pre- to post-education. Pack years were documented in 31%of the records post-education. Prior to education, quit date was documented in 8% of former smokers with an increase to 19% post education.

To determine LCS eligibility, documentation for patients age 55 -77 was reviewed for a quit date equal or less than 15 years for former smoker and for pack years equal or greater than 30 years for current and former smokers (Table 17).

Table 17

Results of LCS Eligibility – AMC

		LCS Eligible		**Not Eligible**		**Unable to Determine**	
	n	**n**	**%**	**n**	**%**	**n**	**%**
Pre-Education	**74**	**4**	**5**	**19**	**26**	**51**	**69**
Former Smoker	48	0		15	31	33	69
Current Smoker	14	4	29	1	7	6	43
Not documented	12					12	100
Post-Education	**77**	**7**	**9**	**22**	**29**	**48**	**62**
Former smoker	53	0		19	36	34	64
Current Smoker	16	7	44	3	19	6	38
Not documented	8					8	100

LCS = lung cancer screening. AMC = Ashley Medical Center.

Based upon the documentation no former smokers were eligible for LCS screening, either pre- or post-education. A 15% increase in current smokers eligible for LCS was noted from pre- to post-education. Records containing insufficient documentation to determine LCS eligibility decreased from 69% (n = 51) pre-education to 62% (n = 48) post-education.

A two-sample t-test was performed to determine whether there was a significant difference between the pre- and post-education percentages for patients in which LCS eligibility was unable to be determined, between the pre- and post-education percentages for patients eligible for LCS, and between the pre- and post-education percentages for current smokers eligible for LCS. The decrease of pre- to post-education patients in which LCS eligibility was

unable to be determined was not significant at the 0.5 alpha level, $t(149) = 0.904$, $p = .3674$. Likewise, the increase in the patients found to be eligible for LCS was not significant at the 0.5 alpha level, $t(149) = 0.961$, $p=.3383$ and the increase in the percentage of current smokers found to eligible for LCS was not significant at the 0.5 alpha level $t(28) = 0.849$, $p = .4031$.

Objective 2d

Objective 2d assessed for an increase number of SDM discussion initiated between rural primary care providers and patients identified at high-risk for lung cancer. Data for this objective were collected by retrospective chart audit as previously discussed. After identifying patients that meet criteria for LCS eligibility and before LCS with LDCT, SDM discussion is required. Components of the SDM discussion have been previously discussed.

Redfield. Results of chart audit for documented SDM discussion for LCS eligible patients for pre-education period, June 2019 through July 2019, and post-education period of November 20, 2019 through January 20, 2019 are found in Table 18.

Table 18

Results of Documented SDM – Redfield

		Patients eligible for LCS		**Documented SDM**	
	n	**n**	**%**	**n**	**%**
Pre-Education	**249**	**4**	**2**	**0**	
Former smokers	167	1	25	0	
Current smokers	81	3	75	0	
Post-Education	**236**	**17**	**7**	**5**	**2**
Former smokers	157	3	18	3	100
Current smokers	77	10	59	2	20
Excluded for CT in past 12 months		4	23		

SDM = shared decision-making. LCS = lung cancer screening.

Of the patient records (age 55 - 77) reviewed, only 2% (n = 4) pre-education and 7% (n = 17) post-education were eligible for LCS based upon documentation in the record. Current

smokers accounted for three-quarters of the eligible patients pre-education and over half of the eligible patients post-education. None of the eligible patients (former or current) had documentation supporting SDM pre-education. Post-education, of the 17 patients identified as eligible for LCS, 29% had a documented SDM discussion that included all the CMS required elements. In addition, all the former smokers had SDM documentation. Nearly a quarter (23%) of the LCS eligible patients post-education was excluded for LCS due to documentation of a diagnostic CT during the previous 12 months.

A two-sample t-test was performed to determine whether there was a significant difference between the pre- and post-education percentages for SDM documentation. The increase of pre- to post-education patients in which LCS was unable to be determined was not significant at the 0.5 alpha level, $t(149) = 0.904$, $p=.3674$. Likewise, the increase in the patients found to be eligible for LCS was not significant at the 0.5 alpha level, $t(149) = 0.961$, $p=.3383$.

AMC. Results of chart audit for documented SDM discussion for LCS eligible patients for pre-education period, June 2019 through July 2019, and post-education period of November 27, 2019 through January 24, 2019 are found in Table 19.

Table 19

Results of Documented SDM – AMC

		Patients eligible for LCS		**Documented SDM**	
	n	**n**	**%**	**n**	**%**
Pre-Education	**74**	**4**	**5**	**0**	
Former smokers	48	0			
Current smokers	14	4	100	0	
Post-Education	**77**	**7**	**9**		
Former smokers	53	0			
Current smokers	16	6	86	0	
Excluded for lung cancer		1	14		

SDM = shared decision-making. AMC = Ashley Medical Center. LCS = lung cancer screening.

Of the patient records (ages 55 - 77) reviewed, only 5% (n = 4) pre-education and 9% (n = 7) post-education were eligible for LCS based upon documentation in the record. Current smokers made up all the documented eligible patients in both the pre- and post-education period. None of the eligible patients had documentation supporting SDM for both pre- and post-education period. Post-education 14% (n = 1) of the eligible patients were excluded for documentation of a lung cancer diagnosis.

Objective 2e

Objective 2e assessed for an increase number of referrals for LDCT or to specialists for LCS in eligible patients at high-risk for lung cancer. Data for this objective were collected by retrospective chart audit as previously discussed. After determining eligibility and following SDM discussion in which the patient and provider decide to proceed with LCS, the next step is to place a referral for LDCT or to a specialist.

Redfield. Results of chart audit for documented LDCT or a specialist referral for LCS eligible patients with documented SDM discussions for pre-education period, June 2019 through July 2019, and post-education period of November 20, 2019 through January 20, 2019 are found in Table 20.

Table 20

Results of LDCT or Specialist Referral – Redfield

	LDCT / Specialist Referral		Decision pending		Not documented	
Documented SDM	**n**	**%**	**n**	**%**	**n**	**%**
Pre-Intervention (n = 0)						
Former smokers	0		0		0	
Current smokers	0		0		0	
Post-Intervention (n = 5)						
Former smokers	1	20	0		0	
Current smokers	0		2	40	2	40

LDCT = low-dose computed tomography. SDM = shared decision-making. LDCT = low-dose computed tomography.

Of the pre-education records reviewed, no patients had documentation of SDM discussion, or a LDCT or to specialist referral. Post-education, 60% of the patients with SDM discussion had documentation of either a LDCT or to specialist referral, or documentation indicating the patient was considering their options. The documented LDCT order was documented for a former smoker.

AMC. Results of chart audit for documented LDCT or a specialist referral for LCS eligible patients with documented SDM discussions for pre-education period, June 2019 through July 2019, and post-education period of November 27, 2019 through January 24, 2019 are found in Table 21.

Table 21

Results of LDCT or Specialist Referral – AMC

	LDCT / Specialist Referral		Decision pending		Not documented	
Documented SDM	**n**	**%**	**n**	**%**	**n**	**%**
Pre-Intervention (n = 0)						
Former smokers	0		0		0	
Current smokers	0		0		0	
Post-Intervention (n = 0)						
Former smokers	0		0		0	
Current smokers	0		0		0	

LDCT = low-dose computed tomography. AMC = Ashley Medical Center. SDM = shared decision-making.

Of the records reviewed both pre- and post-education, no patients had documentation of a SDM discussion, or a LDCT or specialist referral.

CHAPTER FIVE. DISCUSSION AND RECOMMENDATIONS

Interpretation of Results

The purposes of this practice improvement project were (a) to increase the knowledge of rural primary care providers regarding LCS guidelines and the related CMS requirements and to increase their confidence in initiating SDM discussions through the development and implementation of LCS education and (b) to determine the impact of the project. The project included the development and implementation of an educational intervention, consisting of an education session and toolkit, regarding LCS guidelines, related CMS requirements and SDM. Implementation occurred over two-months. The impact of the intervention was evaluated through pre-, immediate post-, and two-month post-education surveys and retrospective chart audit. The results of the project indicated an increase in provider knowledge of LCS guidelines and CMS requirements. In addition, both sites demonstrated a small increase in the number of patients eligible for LCS based on documentation in the EHR.

Objective One

The first objective was to develop and implement an educational intervention consisting of LCS education session and LCS toolkit, regarding LCS and the CMS required SDM discussion elements to improve the use of published LCS guidelines by providers. This objective was evaluated through the use of a five-point Likert scale on the LCS education and toolkit evaluation. All participants strongly agreed that the objectives of the education presentation were met and either strongly agreed or somewhat agreed that the content of the LCS education presentation and toolkit met educational needs, was easy to understand, and free of bias. The majority (88%) of participants strongly agreed or agreed that the content of the LCS education presentation and toolkit content was beneficial to practice. From these results a conclusion can

be reasonably made that as the participating providers at Redfield and AMC reported a benefit of the educational intervention to practice, objective one, to improve use of the published guidelines, was met.

Objective Two

The second objective was to determine the impact of the educational intervention and was divided into five sub-objectives. The objective was evaluated with pre-, immediate post-, and post-education surveys and retrospective chart audit. Caution is exercised in determining inferences from the results of the pre-, immediate post-, and two-month post-education surveys due to the small, purposive sample with low response rate. Of the eight potential responders, five completed the pre- and immediate post-education surveys, with three of the five completing the two-month post-education survey.

Objective 2a

Objective 2a assessed for an increase in the knowledge of rural primary care providers regarding LCS guidelines and the related CMS requirements for LCS and SDM discussions. All participants were defined as having high knowledge of LCS as measured by correctly answering questions four, six and seven on the immediate post- and two-month post-education survey in comparison to 20% of the participants prior to the educational intervention.

In addition, knowledge was measured as a continuous variable, with least knowledge having zero correct and the most knowledge having all six items correct. The most knowledge was found immediate post-education with 100% of participants correctly answering five (20%) or six (80%) of the six items correctly. Prior to the educational intervention, all participants answered four (40%) or less items correctly. The two-month post-education survey found the majority of participants (66%) answering five (33%) and six (33%) of the six items correctly with the remaining participants (34%) answering four items correctly. This is more than the pre-

education but slightly less than immediate post-education. Thus, an increase in knowledge of LCS guidelines was found following the educational intervention. Similar to Lewis et al. (2019), this study initially found a low level of LCS knowledge by providers. This study showed an increase of LCS knowledge following education.

Similar results were noted related to knowledge of CMS requirements for LCS and SDM. Prior to the educational intervention none of the participants correctly identified the CMS requirements for LCS and SDM. The most correct responses were identified immediately post-education with all participants (n = 5) correctly identifying the CMS requirements for LCS and SDM. A slight decrease was noted in the two-month post education with 2 of the 3 participants correctly identifying the CMS requirements for LCS and SDM. Thus, the most knowledge for LCS and SDM was found immediately post-education. A conclusion can be made that the knowledge of LCS guidelines and the related CMS requirements for LCS and SDM discussions increased and was at a high level of knowledge following the educational intervention, thus, Objective 2a was met.

Objective 2b

Objective 2b assessed for an increase in confidence in initiating SDM discussions following the educational intervention. This objective was evaluated through the use of a three-point Likert scale. An increase in confidence was noted from pre-education to immediate post-education, however, the increase was not significant.

Research regarding SDM discussion for LCS have reported variable use (Carter-Harris et al., 2016; Lowenstein et al., 2019). Carter-Harris et al. (2016), reported SDM discussion in less than 20% of screening-eligible current and former smokers, with provider education listed as "crucial in order to enhance patient-provider discussions" (Discussion section, para. 3). In

addition, Lowenstein et al. (2019), found that physicians reported a more thorough SDM discussions than was perceived by patients. Likewise, Detterbeck et al. (2013) identified a lack of awareness and knowledge of LCS guidelines as adding to the challenges of SDM. These studies illustrate the importance of provider education to increasing SDM discussions. Although not statistically significant, this study did find that education increased confidence in initiating SDM.

Objective 2c

Objective 2c assessed for an increase in the number of patients identified at high risk for lung cancer and eligible for LCS. At Redfield, from pre-education to post-education, the percent of charts reviewed that did not have enough documentation to determine eligibility decreased from 82% to 73%, demonstrating a significant decrease. Of the charts with enough documentation, those eligible for LCS increased from 2% to 7%, demonstrating a significant increase.

Similar to Redfield, AMC, from pre-education to post-education, found that the percent of charts reviewed that did not have enough documentation to determine eligibility decreased from 69% to 62%, although not statistically significant, this decrease was clinically significant. Of the charts with enough documentation, those eligible for LCS increased from 5% to 9%. Again, this was not a statistically significant increase, it was clinically significant.

For both Redfield and AMC, from pre-education to post-education, the percent of charts reviewed identifying current smokers as eligible for LCS increased. Redfield demonstrated a significant increase from 4% to 17%. For AMC, the increase of 29% to 44% of current smokers identified as eligible for LCS was not significant.

Results for AMC indicate that there was not enough evidence to conclude that the difference was significant. One assumption is the smaller sample size at AMC compared to Redfield. Larger samples provide more information about a population, thus by increasing the sample size the power of the statistical test is increased (Interpret the key results for 2 proportions, n.d.).

Kinsinger et al. (2017) noted that 39% of patients were unable to be screened due to inconsistent or lack of quit date and pack year documentation. In this study, both sites showed a decrease in the percentage of patients lacking documentation to determine eligibility and an increase in the percentage of patients determined as eligible for LCS; with significant changes in the Redfield Clinic.

The most important part of a screening program is the identification of individuals who will benefit the most from the screening interventions and experience the least amount of harm. Although this project demonstrated an increase in the identification of patients eligible for LCS, of note should be the missed opportunities for identification of eligible patients related to inconsistent or missing documentation. Post-education 73 % (n =172) of patients at Redfield and 62% (n = 48) of patients at AMC were missing key documentation to determine eligibility. This finding is similar to the VHA study that recognized identifying patients eligible for LCS as a significant challenge to the implementation of LCS (Kinsinger et al., 2017).

A conclusion can be made that this objective was met by both sites demonstrating a decrease in the percentage of patients in which eligibility was not able to be determined, as well as an increase in the percentage of patients identified as eligible for LCS.

Objective 2d

Objective 2d assessed for an increase in the number of SDM discussions initiated between rural primary care providers and patients at high-risk for lung cancer. For Redfield, none of the four patients identified as eligible for LCS prior to the educational intervention had a documented SDM discussion. Post-education, 29% of patients identified as eligible for LCS, had a documented SDM discussion and included all the CMS required elements. Interestingly, of the former smokers, all eligible for LCS had a documented SDM discussion. For AMC, no SDM discussions were identified in the pre- or post-education chart audit. A conclusion can be made that for site one this objective was met.

Objective 2e

Objective 2e assessed for an increase in the number of referrals for LDCT or to specialists for LCS in eligible high-risk patients. Prior to the intervention, this data were not obtained for either site as there were no patients with documented SDM discussions. Post-educational intervention, at the first site, 20% of the five patients with a documented SDM discussion were referred for LDCT. Of the four patients without a referral, 40% had documentation that the patient was considering their options. For the second site, this data were not obtained as there were no patients with documented SDM discussions for the post educational intervention. A conclusion can be made that for site one this objective was met.

The increase in the percentage of patients noted for this objective was small. This project was similar to the practice improvement project by Cloonan (2017), in that both incorporated a two-month implementation period. The short implementation period was considered to play a part in the lack of improvement in LCS referrals noted by Cloonan (2017) and for the small improvement noted by this co-investigator. In addition, those patients still considering their

options at the time of data collection for this co-investigators project, may eventually agree to the referral.

Taking into account that few patients were documented as eligible for LCS, documentation of even a small number of SDM discussions is a positive finding for this project. The Revised Iowa Model (2017) includes evaluation steps to promote adoption and to reinfuse the project as needed. Implementation of LCS guidelines is a complex process. The results show promise with continued evaluation.

Results Summary

This project found that the educational intervention improved provider use of published LCS guidelines and increased provider knowledge of LCS guidelines and the related CMS requirements. Although not a significant change, the educational intervention also increased provider confidence in initiating SDM discussions. In addition, the intervention improved documentation to determine eligibility and increased the percentage of patients identified at high risk for lung cancer and eligible for LCS; with one of the two implementation sites experiencing significant changes. At one intervention site, of those patients identified as eligible for LCS, almost one-third had a documented SDM discussion; this was an increase from no documented SDM discussions for eligible patients prior to the educational intervention. At the same intervention site, of the five patients eligible for referral, one patient was referred for LCDT and two patients were still considering referral.

The positive findings for this project are promising to rural providers. Lewis et al. (2019) found primary care providers lack awareness of recommended guidelines and are apprehensive with ordering LDCT for LCS. Lack of awareness and lack of knowledge of LCS guidelines by rural providers have been noted as a deterrence to SDM (Jenkins et al., 2018). This project

addressed the elements and requirements for SDM and found a clinically, but not statistically significant, increase in provider confidence in initiating SDM, thus emphasizing the importance of education for rural providers. Education provided in the context of this project demonstrated an increase in knowledge and identification of patients eligible for LCS. In addition, system barriers in rural areas, including lack of access to LDCT, leads to decreased LCS (Hoffman et al., 2015). Both sites indicated an increase in the patients identified for LCS, however, only Redfield had documented referral for LDCT following the education. This could be in part that Redfield is performing LDCT on site, while at the time of the project, AMC was not performing the procedure,

Recommendations

Results of this project support the need for additional research on the evaluation of provider education on the implementation of LCS guidelines. Research addresses provider perception of LCS guidelines and overall knowledge, however, is limited in the effect of education on the implementation and use of LCS guidelines (Lewis et al, 2019). Implementation of LCS guidelines is a complex process that requires a well thought out organizational process for success. Continued evaluation is recommended to address any future educational and process gaps.

A recommendation for additional education would be to offer education in multiple formats. This would fit into the Adult Learning Theory principles of readiness to learn, prior experience, self-directed learning, and the need to know (Merriam, 2018). Use of an online interactive module with multiple patient scenarios is one format to consider.

Another recommendation is to provide LCS education to patients. Bryne et al. (2019), noted that a thorough understanding of factors affecting patient awareness and knowledge of

LCS is vital in engaging patients in effective SDM discussions. Decision aids are an important tool for facilitating SDM and it would benefit the organizations to personalize decision aids for their patients (Cloonan, 2017).

Implementation of the project at each site provided unique challenges. Recommendations for both sites would be to focus on the consistent documentation of quit date for former smokers, and pack history for current and former smokers. Lung cancer screening is more than a single test, it is complex process that begins with the identification of a population with sufficient risk and low enough competing risks (Detterbeck, 2013). Mazzone et al. (2018), reported on implementation challenges of LCS to include difficulty identifying eligible patients due to incomplete smoking history information and inconsistent use of EHR tools and documentation.

Finally, a recommendation for both sites would be to follow the Iowa Model with continued evaluation, monitoring of key indicators, and re-infusing to hardwire the change into the system (Iowa Model Collaborative, 2017). According to the Iowa Model Collaborative (2017), "hardwiring occurs when evidence-based practice is the default approach, done automatically within the workflow" (p. 180). To improve success, a recommendation is to collaborate with information technology as the majority of data collection for this project was manual abstraction of the chart.

Limitations

Several limitations were associated with this practice improvement project. The first limitation was the limited number of education sessions. One education session was held at each site. Limiting the education session to one time at each site, limits the number of participants to the availability at the time of the session. In addition to the limited number of sessions, the education sessions were held as part of another regular scheduled meeting. At both sites the

education was conducted in the first part of the meeting limiting time for discussion and questions. This may have played a part in decreased survey completion, especially for physicians as no physician completed surveys.

Another limitation to this project is sample mortality. In research, mortality refers to participants who have dropped out of the study or did not complete the process (Wright & Lake, n.d.). Sample mortality is common in pre-test/post-test project designs, small samples, and with long periods of time between surveys (Wright & Lake, n.d.), such as this project.

The small sample size can be considered a limitation. Small sample size can negatively impact results by limiting the ability generalize the results. The Iowa model offsets these limitations by taking into account the intent of the project, which is to improve quality and safety within the local clinical setting by applying evidence, for this project the implementation of LCS guidelines, into practice (University of Iowa Hospitals and Clinics, n.d.). The scope of interest endorsed by the Iowa Model is a specific unit or population within an organization. In the context of rural healthcare, this often leads to small sample sizes.

Consistent documentation in the electronic medical record is another limitation. Each site used a different electronic medical record system with differing capabilities. Understanding the capabilities of the medical record was a limitation of the co-investigator. Documentation regarding SDM and LDCT or specialist referral may have been missed related to the co-investigator's limited understanding of the EHR and inconsistent documentation in the record.

Aggregating the data resulting from survey results can be considered a limitation. Aggregate form was used to protect provider identities in both sites; however, the aggregation of data does not allow for the results to be tailored to the individual sites or providers. In addition, the aggregate data does not allow for the determination of individual provider knowledge and

LCS referrals. Knowledge of this information would help to follow-up and tailor further education to meet the provider needs. Knowles' principles identify motivation to learn, readiness to learn, and need to know as characteristics of the adult learner (Merriam, 2018). The ability to provide individual data to providers supports these principles.

Identified as another limitation was the amount of time allotted for data collection and monitoring. The data were collected for a two-month period prior to the start of the educational intervention and again for two months following the intervention. The amount of time may have not been adequate to identify screening patterns prior to the educational intervention. In addition, the amount time following the intervention may not have been adequate to fully see changes. As previously discussed, continued use of the Iowa model to evaluate and re-infuse overtime will help to realize continued improvements.

Implications for Practice

This practice improvement project involved two different clinical sites, including physicians, advanced practice providers, nursing staff and clinic support staff. The data collected adds to the available literature regarding the impact of healthcare professional-focused educational interventions. The results of the project support the need for increased use of LCS guidelines and continued evaluation of project objectives. The co-investigator found that knowledge regarding LCS was low prior to the project, with the most knowledge gained immediately after the education session, and remained at a high level even two months post-intervention. Continued educational support is needed as identification of patients eligible for LCS is a complex process involving the nursing staff and providers.

New information was provided during the educational intervention project to increase healthcare professional knowledge about the significance of lung cancers and importance of

early detection through screening. Lung cancer is accountable for more deaths than any other cancer (ACS, 2019a). Improving identification and screening of eligible patients will lead to reduced lung cancer mortality (De Koning et al. 2018).

An important part of the lung cancer screening process is SDM. The small increase in SDM discussions demonstrated in the project is promising. Continued education and evaluation are needed for further increases. In addition, smoking cessation is an important aspect of LCS (Mishra et al, 2016). This project did not specifically address smoking cessation. Documentation of smoking cessation counseling is a requirement of CMS (2015), however was not a focus of this project, yet is an important implication for practice.

Implications for Future Research

Additional research is needed in implementation processes of LCS. Specifically, research to improve consistent documentation of quit dates and pack years could improve determination of LCS eligibility of patients. Identification of eligible patients is the first and one of the most important part of the screening process.

Another area of focus for future research is the rural population. Limited research is available for LCS implementation in rural healthcare. Rural areas are often face with limited resources, decreased access, and lack of awareness of recommended guidelines (Jenkins et al., 2018).

Application to DNP Roles

Nurse practitioners in primary care and family practice are ideally positioned to screen patients and educate regarding LCS. Nurse practitioners improve the health of the population and provide education to patients. Increased screening and opportunities for prevention through smoking cessation has the potential to improve health and reduce lung cancer mortality.

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APPENDIX A. LITERATURE REVIEW SEARCH STRATEGY

Identification

Literature Search Databases

	"lung cancer screening" AND "guidelines"	*"lung cancer screening" AND "guidelines" AND "shared decision-making"*	*"lung cancer screening" AND "guidelines" AND "implementation"*	*"lung cancer screening" AND "guidelines" AND "implementation" AND "primary care"*
Web of Science	n = 668 n*= 19	n = 36 n* = 6	n = 91 n* = 2	n = 18 n* = 0
PubMed	n = 954 n* = 42	n = 11 n* = 1	n = 5 n* = 5	n = 5 n* = 0
MEDLINE	n = 89 n* = 19	n = 10 n* = 1	n = 11 n* = 1	n = 3 n* = 0
Cochrane Reviews	n = 4 n* = 0	n = 0 n* = 0	n = 1 n* = 0	n = 0 n* = 0
Trials	n = 131 n* = 20	n = 6 n* = 0	n = 23 n* = 6	n = 7 n* = 0

Limits: 2013 to April 2019; n = April 2019 to January 30, 2020*
Exclusions applied (non-English, radiology-based studies, observational design, non-smokers, ages other than 55 to 80 years, editorials, and commentaries) and duplicates removed: n = 1585; n = 100*

Screening

Abstracts screened for inclusion (n = 474; n* = 22)
Removed (n = 220; n* = 10)
Added (n = 13; n* = 0)

Inclusions (age 55 to 80, lung cancer screening interventions, guidelines, implementation of lung cancer screening in primary care, provider knowledge and SDM)

Additional records identified through other sources (Google scholar, secondary bibliography search, CDC, AHQR)
n = 13; n* = 0

Eligibility

Full-text articles screened for eligibility
(n = 267; n* = 12)

Exclusion reasons:
Interventions not specific to lung cancer screening
(n = 146; n* = 6)
Inappropriate population (n = 40; n* = 1)
Interventions not related to primary care (n = 21; n* = 1)

Included

Included in final evidence review
(n = 36; n* = 4)

APPENDIX B. CMS LUNG CANCER SCREENING REQUIREMENTS

Medicare beneficiaries considered high risk:

- Age 55 – 77 years old
- No current signs or symptoms of lung cancer
- At least a 30 pack-year history of tobacco smoking
- Current smoker or former smoker who quit within the past 15 years
- Written order for LDCT lung cancer screening

Documentation required as part of LDCT lung cancer screening order:

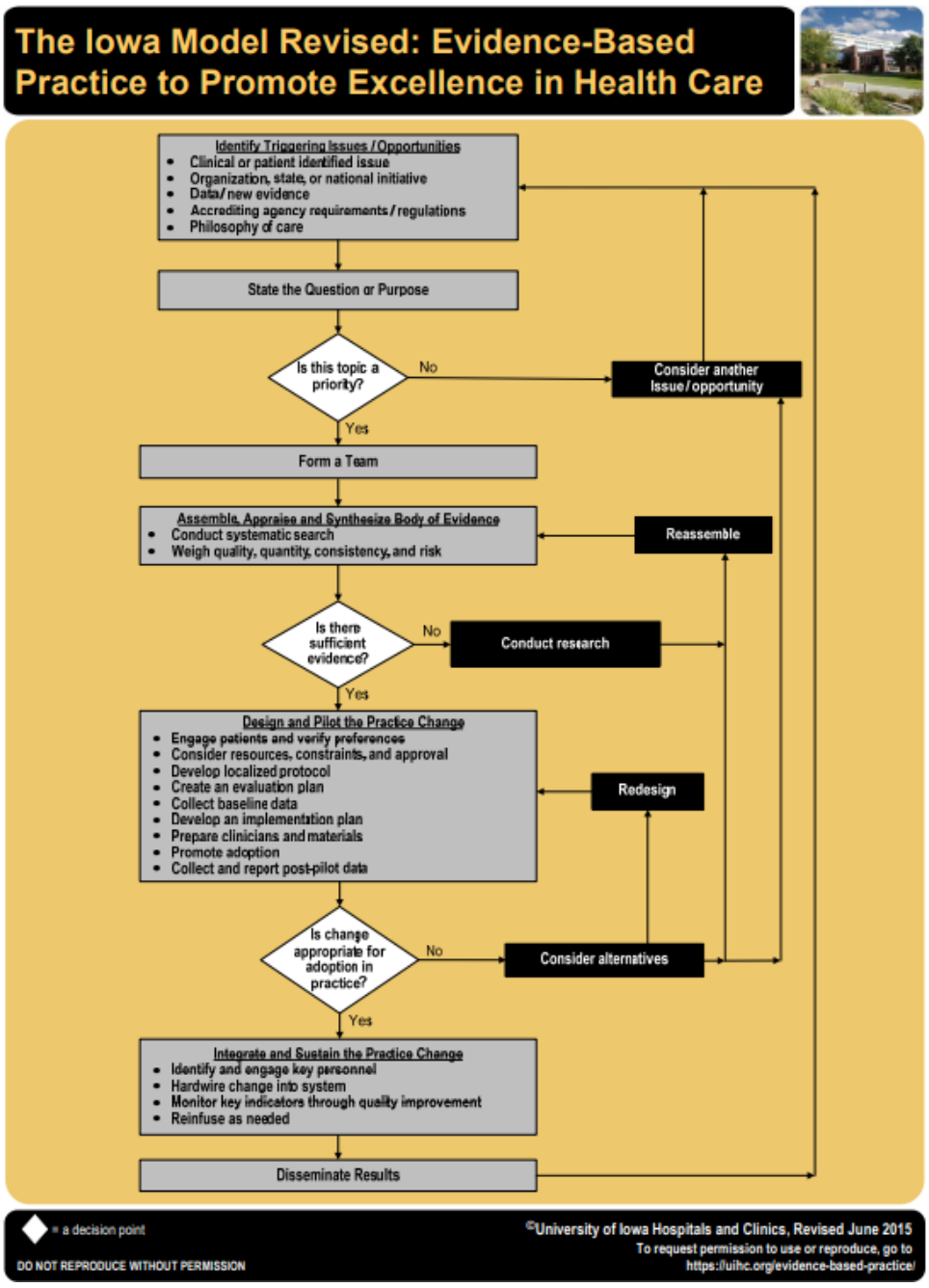
- Date of Birth
- Pack-year history of tobacco smoking
- Smoking status; if former smoker, the number of years since cessation
- Lack of signs and symptoms concerning for lung cancer
- The ordering provider's National Provider Identifier (NPI)

Beneficiary receives written order for LDCT lung cancer screening during a lung cancer screening counseling and shared decision-making visit provided by a physician or qualified non-physician practitioner (physician assistant, nurse practitioner, clinical nurse specialist). The following elements must be met and documented as part of shared decision-making:

- Determination of beneficiary eligibility for screening (age, lack of signs or symptoms of lung cancer, pack-year history of tobacco smoking, and number of years since quitting, if a former smoker).
- Shared decision-making using one or more decision aids; must include benefits and harms of screening, follow-up diagnostic testing, over-diagnosis, false positive rate, and total radiation exposure.
- Counseling to include the importance of adhering to annual lung cancer screening with LDCT, impact of comorbidities, and ability/willingness to be diagnosed and treated.
- Counseling for former smokers regarding the importance of sustaining tobacco smoking abstinence; and for current smokers the importance of smoking cessation. If appropriate, information is provided about smoking cessation interventions.
- When appropriate the provision of a written order for lung cancer screening with LDCT.

(Centers for Medicare and Medicaid Services, 2015)

APPENDIX C. IOWA MODEL



APPENDIX D. PERMISSION TO USE THE IOWA MODEL

Permission to Use the Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care

Kimberly Jordan - University of Iowa Hospitals and Clinics <noreply@qualtrics-survey.com>
Tue 3/12/2019 9:12 AM

To: Formo, Teresa <teresa.trapp@ndsu.edu>

You have permission, as requested today, to review and/or reproduce *The Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care.* Click the link below to open.

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> In written material, please add the following statement:
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Please contact UIHCNursingResearchandEBP@uiowa.edu or 319-384-9098 with questions.

APPENDIX E. EXECUTIVE SUMMARY

Lung Cancer Screening: Identification of High-Risk Patients and Shared Decision-Making

Lung cancer is often diagnosed at a late stage, rendering it the most common cause of cancer related deaths in the United States. Screening with low-dose computed tomography decreases lung cancer mortality by 20%. Current guidelines support lung cancer screening (LCS), yet less than 5% of eligible patients are screened for lung cancer.

Lung cancer screening is a complex process that begins with the identification of eligible patients and the initiation of shared decision-making (SDM). Identification of patients eligible for LCS is a logical extension to the documentation of patient smoking status already collected in primary care.

LCS Eligibility

USPSTF	CMS
55 – 80 years	*55 – 77 years*
Current smoker	
Former smoker quit ≤ 15 years	
≥ 30 years pack history	

Lung cancer screening, including the SDM discussion, is reimbursable by CMS and insurance companies.

RECOMMENDATIONS

For the organizations to continue improvement in the identification of patients eligible for LCS and SDM, the following recommendations are made:

- Reinforce education to providers and clinic staff regarding the need for consistent documentation to increase the number of patients with enough documentation to determine LCS eligibility.
- Add reminders to charts for patients that are eligible for screening, currently being screened, and those refusing screening, to improve screening process.
- Continue to evaluate the LCS process by periodic chart audits for documentation and referrals.
- Evaluate SDM discussions for documentation and charge capture.
- Provide education to patients to enhance SDM discussions.

Lung Cancer Screening Executive Summary

PROJECT SUMMARY

The purpose of the project was to increase the knowledge of rural primary care providers at Redfield Clinic and Ashley Medical Center, regarding lung cancer screening guidelines and related CMS requirements and to increase their confidence in initiating shared decision-making discussions.

An educational intervention, consisting of a LCS education session and a LCS toolkit were developed for the project sites. The education sessions and toolkits were presented to Redfield Clinic on November 20, 2019 and Ashley Medical Center on November 27, 2019.

Impact of the project was assessed through (a) provider surveys collected pre-, immediate post-, and two-month post-education and (b) a chart audit collected pre- and two-month post education.

RESULTS

Provider Surveys (Pre-, Immediate Post-, and Two-Month Post-Education)

- Providers reported a benefit to the educational intervention.
- Providers exhibited an increase of knowledge in LCS guidelines and CMS requirements from pre- to two-month post-education with the greatest knowledge exhibited at immediate post-education and a high level of knowledge remaining at two months post-education.
- Providers reported a small increase in confidence in initiating SDM discussions.

Chart Audit (Pre-education to Post-education)

- Charts reviewed showed an increase in the percent of charts that had enough documentation to determine eligibility.
    - Redfield from 73% to 82%; a significant change
    - AMC from 62% to 69%
- Charts with enough documentation to determine patients at high risk for lung cancer demonstrated an increase in patients identified as eligible for LCS.
    - Redfield from 2% to 7%; a significant change
    - AMC from 5% to 9%
- Charts reviewed at Redfield demonstrated an increase in the number SDM discussions and referrals for LDCT. AMC did not have any documented SDM discussions or referrals for LDCT or specialist during the chart audit periods.

APPENDIX F. IRB APPROVAL

NDSU NORTH DAKOTA STATE UNIVERSITY

October 15, 2019

Dr. Kelly Buettner-Schmidt
Nursing

Re: IRB Determination of Exempt Human Subjects Research:
Protocol #PH20084, "Lung Cancer Screening Identification of high-Risk Patients and Shared Decision-Making"

Co-investigator(s) and research team: Teresa Formo
Date of Exempt Determination: 10/15/2019 Expiration Date: 10/14/2022
Study site(s): Ashley Medical Center and Redfield Clinic
Sponsor: n/a

The above referenced human subjects research project has been determined exempt (category #1, 4(ii)) in accordance with federal regulations (Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects). This determination is based on the original protocol submission (received 10/11/2019).

Please also note the following:
• If you wish to continue the research after the expiration, submit a request for recertification several weeks prior to the expiration.
• The study must be conducted as described in the approved protocol. Changes to this protocol must be approved prior to initiating, unless the changes are necessary to eliminate an immediate hazard to subjects.
• Notify the IRB promptly of any adverse events, complaints, or unanticipated problems involving risks to subjects or others related to this project.
• Report any significant new findings that may affect the risks and benefits to the participants and the IRB.

Research records may be subject to a random or directed audit at any time to verify compliance with IRB standard operating procedures.

Thank you for your cooperation with NDSU IRB procedures. Best wishes for a successful study.
Sincerely,

Kristy Shirley

Kristy Shirley, CIP, Research Compliance Administrator

For more information regarding IRB Office submissions and guidelines, please consult https://www.ndsu.edu/research/for_researchers/research_integrity_and_compliance/institutional_review_board_irb/. This Institution has an approved FederalWide Assurance with the Department of Health and Human Services: FWA00002439.

INSTITUTIONAL REVIEW BOARD
NDSU Dept 4000 | PO Box 6050 | Fargo ND 58108-6050 | 701.231.8995 | Fax 701.231.8098 | ndsu.edu/irb
Shipping address: Research 1, 1735 NDSU Research Park Drive, Fargo ND 58102

APPENDIX G. LETTER OF INTENT TO IRB

Ashley Medical Center Clinic
612 Center Ave. N.
Ashley, ND 58413
Phone: 701-288-3448

October 11, 2019

NDSU Institutional Review Board
NDSU Department 4000
PO BOX 6050
Fargo, ND 58108-6050

To who it may concern,

This letter is to indicate the intent of the Ashley Medical Center to collaborate in Teresa Formo's practice improvement project, "Lung Cancer Screening: Identification of High-Risk Patients and Shared Decision-Making." This project will start in October of 2019 and end in January of 2020. I am aware of Ms. Formo's intent to provide education regarding lung cancer screening guidelines and CMS requirements for shared decision-making. I understand the knowledge gained by providers will allow for sustained adoption of lung cancer screening guidelines. Staff at Ashley Medical Center Clinic will be encouraged to participate, but participation is voluntary.

As part of this project, Ms. Formo will have permission to review the charts of patients ages 55-80 seen in the clinic during the months of June / July 2019 and for two months following the education (TBD). The charts will be reviewed for documentation of smoking status, quit date, pack year smoking history, shared-decision making discussions and referral for low dose CT or specialist for lung cancer screening. No patient identifiers be collected on the patients and review will take place at Ashley Medical Center.

As part of this project, Ms. Formo has the permission to identify Ashley Medical Center as one of the project settings. The approved NDSU IRB protocol will be followed when conducting the project.

Thank you,

Jennifer Kaseman, LPN
Office Manager
Ashley Medical Center

Redfield Clinic
Redfield Community Memorial
1010 W 1st St.
Redfield, SD 57469
Phone: 605-472-0510 Ext. 7594

October 11, 2019

NDSU Institutional Review Board
NDSU Department 4000
PO BOX 6050
Fargo, ND 58108-6050

To who it may concern,

This letter is to indicate the intent of the Redfield Clinic to collaborate in Teresa Formo's practice improvement project, "Lung Cancer Screening: Identification of High-Risk Patients and Shared Decision-Making." This project will start in October of 2019 and end in January of 2020. I am aware of Ms. Formo's intent to provide education regarding lung cancer screening guidelines and CMS requirements for shared decision-making. I understand the knowledge gained by providers will allow for sustained adoption of lung cancer screening guidelines. Staff at Redfield Clinic will be encouraged to participate, but participation is voluntary.

As part of this project, Ms. Formo will have permission to review the charts of patients ages 55-80 seen in the clinic during the months of June / July 2019 and for two months following the education (TBD). The charts will be reviewed for documentation of smoking status, quit date, pack year smoking history, shared decision-making discussions and referral for low dose CT or specialist for lung cancer screening. No patient identifiers be collected on the patients and review will take place at Redfield Clinic.

As part of this project, Ms. Formo has the permission to identify Redfield Clinic as one of the project settings. The approved NDSU IRB protocol will be followed when conducting the project.

Thank you,

Kristin Baloun RN

Kristin Baloun, RN, BSN
Clinic Director
Redfield Clinic

APPENDIX H. EDUCATION SESSION SLIDES

Lung Cancer Screening

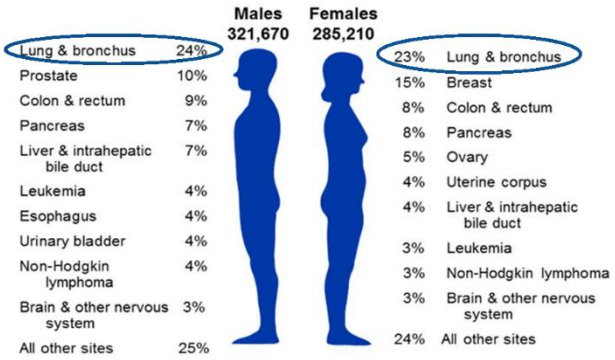
TERESA FORMO, MSN, RN, DNP-STUDENT
NORTH DAKOTA STATE UNIVERSITY
NOVEMBER 20 AND 27, 2019

The purpose of the project is to increase knowledge of providers regarding lung cancer screening (LCS) guidelines, the related CMS requirements and shared decision-making discussions.

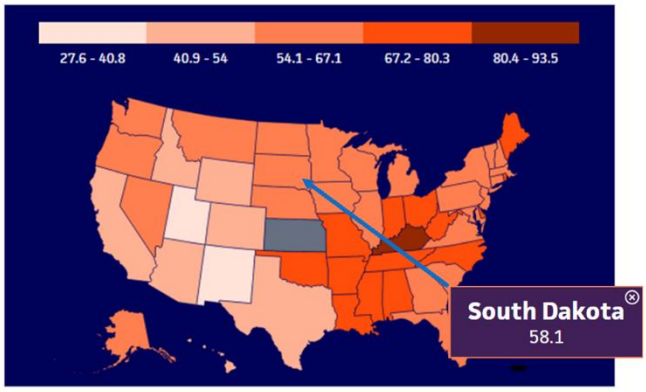
At the conclusion of this activity participants will be able to:

- Summarize the USPSTF and CMS Lung Cancer Screening Guidelines
- Determine the eligibility of patients at high risk for lung cancer
- Initiate LCS shared decision-making discussions
- Identify required elements for documentation of LCS

Estimated Cancer Deaths in the US in 2019



American Cancer Society. (2019a). *Cancer facts & figures 2019*. Retrieved from https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2019/cancer-facts-and-figures-2019.pdf

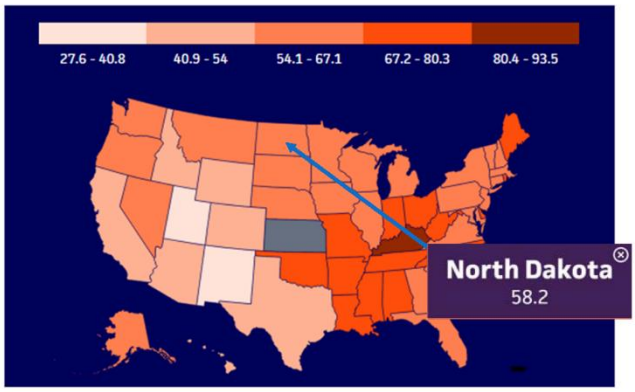


Incidence rates, 2011-2015

National Rate is 56.0

Average annual rate per 100,000, age adjusted to the 2000 US standard population.

American Cancer Society. (2019a). *Cancer facts & figures 2019*. Retrieved from https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2019/cancer-facts-and-figures-2019.pdf



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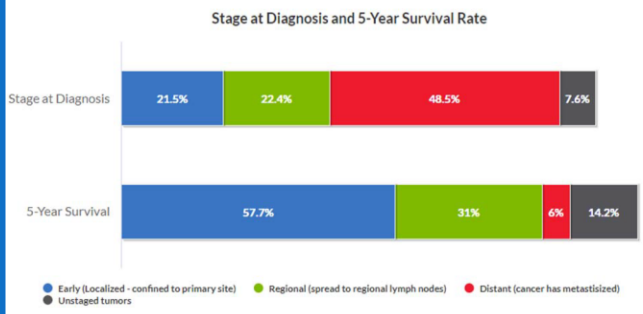
Stage at Diagnosis & 5-Year Survival Rate

- Non-small cell lung cancer (NSCLC)
  - 84% of all lung cancer
- 5-year survival rate is dependent on subtype of lung cancer and stage of disease



In South Dakota, 23.2% of lung cancer is diagnosed at an early stage.
5-year survival rate not tracked in South Dakota

American Lung Association. (2019). *State of Lung Cancer*. Retrieved from https://www.lung.org/our-initiatives/research/monitoring-trends-in-lung-disease/state-of-lung-cancer/

Stage at Diagnosis & 5-Year Survival Rate

- Non-small cell lung cancer (NSCLC)
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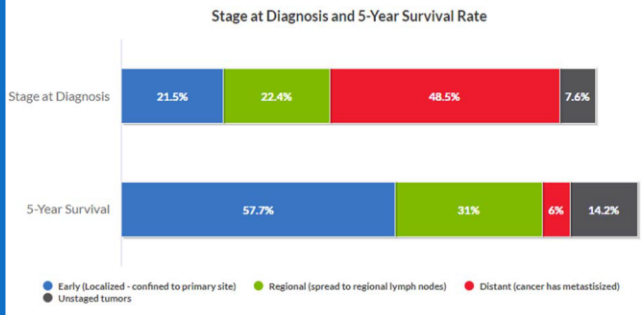


In North Dakota, 22.2% of lung cancer is diagnosed at an early stage.
The 5-year survival rate for North Dakota is 23.3%.

American Lung Association. (2019). *State of Lung Cancer*. Retrieved from https://www.lung.org/our-initiatives/research/monitoring-trends-in-lung-disease/state-of-lung-cancer/

The **Evidence**

Dutch-Belgium NELSON trial

- Published 2018
- Randomized 16000 participants
  - LDCT or no screening
  - screens at baseline, 1, 3 and 5.5 years
  - results showed a 33 – 44% reduction in lung cancer mortality (De Koning et al. ,2018)

National Lung Screening Trial (NLST)

- Published 2011
- Randomized > 53,000 heavy smokers to
  - low dose computed tomography (LDCT) or chest x-ray (CXR)
  - 3 annual screens
  - followed for 6.5 years
  - results found a reduction in lung cancer deaths by 16-20% (NLST,2011)

Multicentric Italian Lung Detection (MILD) trial

- Published 2019
- Randomized 4,099 participants to
  - LDCT or no screening
  - annual or biennial screens for 6 years
  - results found a reduction in lung cancer deaths by 39% at 10 years

(Pastoroni, 2019)

Nancy

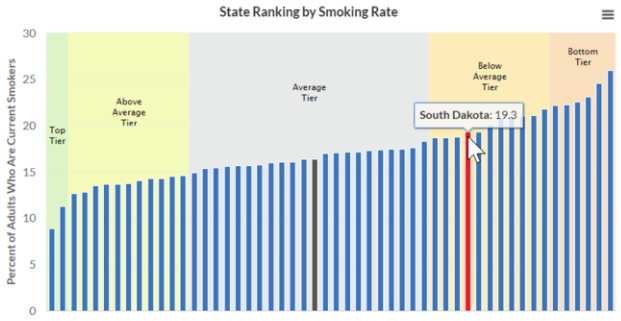
Nancy

- 67 y/o female
- no medical history
- current smoker
- 42-year pack history
- denies alcohol/drug use
- no surgeries
- never married / no kids
- works in the local grocery store
- mother died of lung cancer
- negative exam

Is Nancy eligible for lung cancer screening?

What puts Nancy at risk?

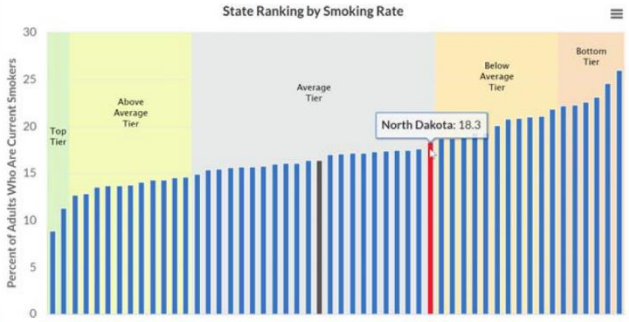
- Cigarette smoking
  - 81% of lung cancer is caused by smoking
  - risk of lung cancer increases with quantity and duration of smoking
  - National smoking rate is 16.4%
- Other risk factors include exposure to:
  - radon gas
  - secondhand smoke
  - asbestos
  - occupational exposures



American Lung Association. (2019). *State of Lung Cancer*. Retrieved from https://www.lung.org/our-initiatives/research/monitoring-trends-in-lung-disease/state-of-lung-cancer/

What puts Nancy at risk?

- Cigarette smoking
  - 81% of lung cancer is caused by smoking
  - risk of lung cancer increases with quantity and duration of smoking
  - National smoking rate is 16.4%
- Other risk factors include exposure to:
  - radon gas
  - secondhand smoke
  - asbestos
  - occupational exposures



American Lung Association. (2019). *State of Lung Cancer*. Retrieved from https://www.lung.org/our-initiatives/research/monitoring-trends-in-lung-disease/state-of-lung-cancer/

U.S. Preventive Services TASK FORCE

Release Date: December 2013

Recommendation Summary

Summary of Recommendation and Evidence

Population	Recommendation	Grade (What's This?)
Adults Aged 55-80, with a History of Smoking	The USPSTF recommends annual screening for lung cancer with low-dose computed tomography (LDCT) in adults aged 55 to 80 years who have a 30 pack-year smoking history and currently smoke or have quit within the past 15 years. Screening should be discontinued once a person has not smoked for 15 years or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative lung surgery.	B

USPSTF (2013)

CMS.gov
Centers for Medicare & Medicaid Services

Decision Memo February 2015

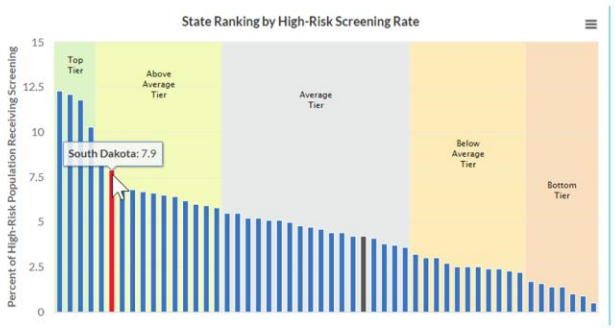
- Medicare covers low-dose computed tomography (LDCT) for lung cancer screening
- Eligibility criteria:
  - Age 55 – 77
  - At least 30 pack yr. hx smoking
  - Current smoker or quit within past 15 yrs
  - Requires Shared Decision-Making visit
  - Requires patient be offered Smoking Cessation services
  - Requires written order for screening CT
  - Patient and exam data must be entered into CMS approved LCS Registry

CMS (2011)

Organization	U.S. Preventive Services Task Force (USPSTF)	Centers for Medicare & Medicaid Services (CMS)
Patient Group	• Individuals with private health insurance	• Medicare beneficiaries
Age	• 55-80 years	• 55-77 years
Smoking status	• Current smoker or former smoker who quit within the past 15 years	
Pack history	• Greater than or equal to 30 years	
Lung cancer signs/symptoms	• Asymptomatic	
Shared decision-making visit	• Required	
Previous lung CT	• None (diagnostic or screening) within the past year	
Screening frequency	• Annually • Based on findings	
Discontinue screening	• Exceed age limit • Greater than 15 years since quit date • Development of health problem that will substantially limit life expectancy • Patient ability or willingness to have curative lung surgery	

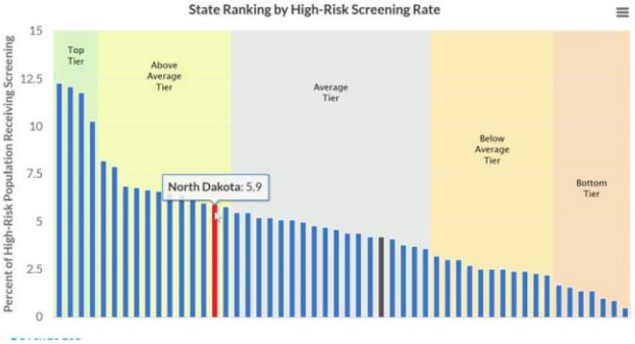
Nancy meets eligibility for screening

- Annual LDCT screening for lung cancer reduces lung cancer mortality by up to 20%
- National screening rate is 4.2% among high risk population
- Low screening rates related to lack of access or low awareness and knowledge
- South Dakota, 1 of 31 states in which Medicaid fee for service covers lung cancer screening



American Lung Association. (2019). *State of Lung Cancer*. Retrieved from https://www.lung.org/our-initiatives/research/monitoring-trends-in-lung-disease/state-of-lung-cancer/

- Annual LDCT screening for lung cancer reduces lung cancer mortality by up to 20%
- National screening rate is 4.2% among high risk population
- Low screening rates related to lack of access or low awareness and knowledge
- North Dakota is 1 of 12 states in which Medicaid fee for service does not cover lung cancer screening



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Shared Decision-Making

- Process to facilitate decisions based on clinical evidence and patient's values
- Lung cancer screening was first modality in which the CMS required documentation of SDM for reimbursement

(Politi, Wolin, & Legare, 2013).

arvin-chingcuangco-1337417-unsplash

CMS Lung Cancer Screening Requirements

- **Decision Aid**
  - Use 1 or more decision aids
- **Discuss**:
  - Benefits & harms of screening
  - Follow-up diagnostic testing
  - Overdiagnosis
  - False positive rate
  - Total radiation exposure
- **Counsel** on:
  - Importance of adherence to annual lung cancer LDCT screening
  - Impact of comorbidities
  - Ability or willingness to undergo diagnosis and treatment
  - Importance of maintaining cigarette smoking abstinence if former smoker
  - Importance of smoking cessation if current smoker
  - Furnishing of information about tobacco cessation interventions

CMS (2011)

Nancy's Shared-Decision Making

- Explore LCS process
  - use of decision aid
  - lung CT process
  - what happens if something is found
  - risks from a biopsy
  - possibility of needing frequent follow up CTs if nodule found
  - smoking cessation
- Assess her values and preferences
  - she does not want frequent contact with health providers
  - doesn't want to worry about cancer
  - her mother died from cancer – horrible
  - mother did not quit smoking and waited until she could barely breathe
  - she is not ready to quit smoking
- Reach a decision
  - Nancy decides to have screening
  - will think about quitting smoking
- Evaluate decision
  - agree benefits outweigh risks

LDCT Lung Cancer Screening Order

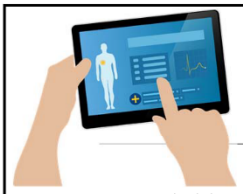
- Date of birth
- Number of pack-years smoked
- Current smoking status, or for former smokers, the number of years since quitting smoking
- Statement that the beneficiary is asymptomatic
- National Provider Identifier (NPI) of ordering provider

CMS (2011)

CT Chest Screen

CT Chest Screening - RX.LCSCREENING

* Patient 55-77 yrs old
* Provider's NPI
* Smoking Status - Ex. Current or Former Smoker:
If former, years since quitting (must be <15 yrs)
* Packs per day
* Number of years smoked
* Pack Years (Must be >30)
* Patient is Asymptomatic (No signs/symptoms lung cancer)
* Chest CT within 1 year? (If Y, Does not qualify)
* Does patient qualify for LDCT? (If Y, proceed with order)
****
* Is there documentation of Shared Decision? (Must have)
* Smoke cessation guidance given to patient? (must provide)
* Counseling given on adherence to annual screening? (must do)
* Prior history of lung cancer
Other cancer related history
Indication for Exam:
* Ex. Annual, Baseline, or Follow-up CT
****
Enter Y next to diagnosis that pertains:
Z87.891 Personal hx of tobacco/personal hx of nicotine
Other Diagnosis:



Documentation

1. Determine eligibility
   - age
   - absence of symptoms
   - pack year calculation
   - number of years since quit
2. Use 1 or more decision aids
   - include benefits, harms, follow-up diagnostic testing, over-diagnosis, false positive rate, total radiation exposure
3. Importance of adherence to annual LDCT, impact of comorbidities and ability or willingness to undergo diagnosis and treatment
4. Counseling on importance of maintaining cigarette abstinence, or furnishing information about tobacco cessation services
5. Written order
   - DOB
   - pack year history (number)
   - smoking status – years since quit
   - statement beneficiary asymptomatic
   - NPI
6. G0296 – counseling visit to discuss need for lung cancer screening LDCT (service is for eligibility determination and shared decision-making)
7. Z87.891 - personal history of tobacco use/personal history of nicotine dependence OR F17.2XX – Nicotine dependence, cigarettes

CMS (2011)

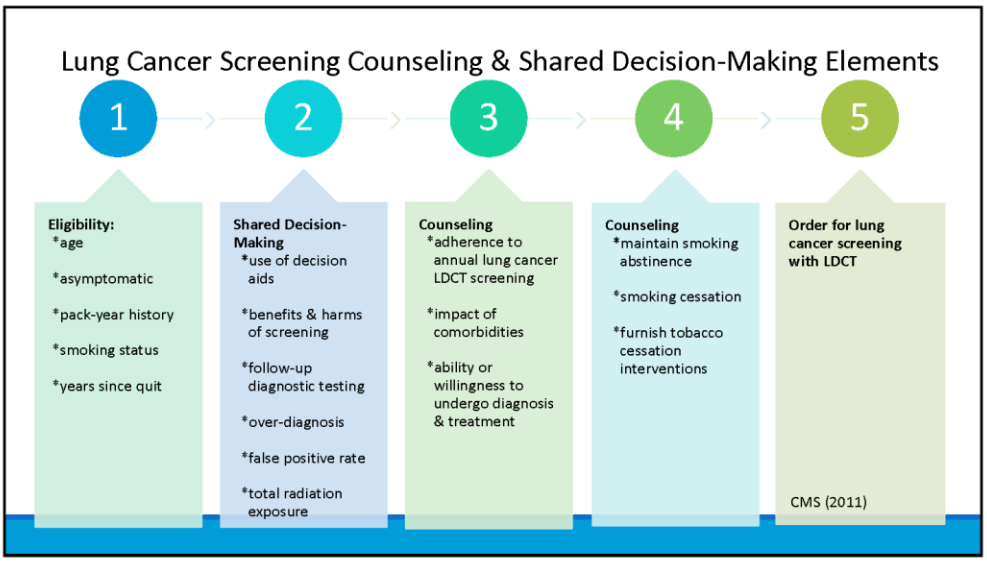
Nancy's Results

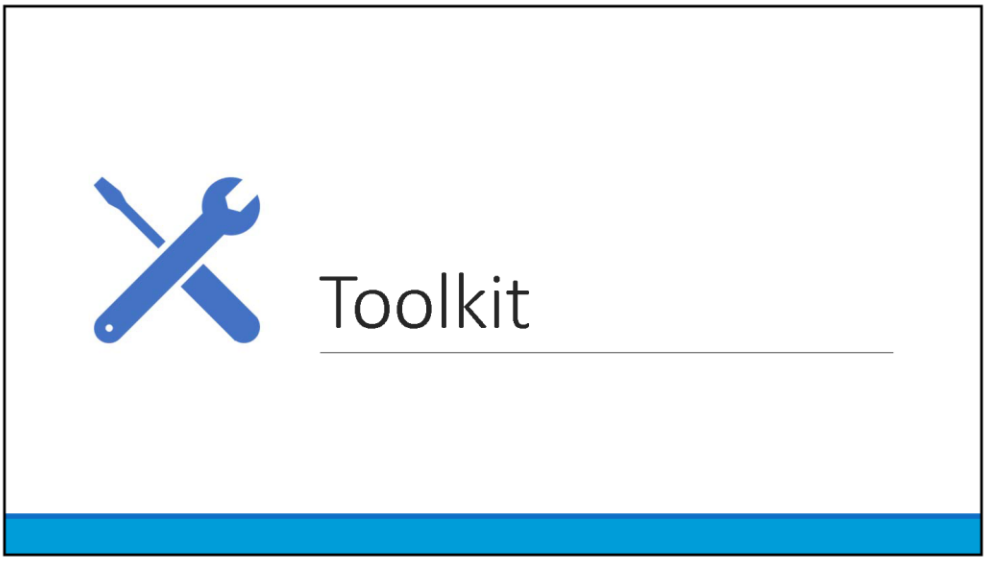
IMPRESSION:
1. Lung Cancer Screening: LungRADS Category 2, Benign appearing (non-actionable) nodule(s). These types of nodules are commonly observed and require no immediate action. Current recommendations for eligible high risk individuals (criteria below) are routine annual screening with low dose CT.
2. Post inflammatory/infarct scarring in RML.

Category	Lung-RADS* Score	Management
Negative	1	Annual LDCT
Benign	2	
Probably Benign	3	6-month LDCT
Suspicious	4A	Referral to specialist, LDCT, PET/CT, tissue sampling based on nodule size
Very Suspicious	4B	

What do the results mean?

Adapted from the American College of Radiology. (2019). *Lung-RADS® Version 1.1* https://www.acr.org/-/media/ACR/Files/RADS/Lung-RADS/LungRADSAssessmentCategoriesv1-1.pdf


Lung Cancer Screening Counseling & Shared Decision-Making Elements
1
2
3
4
5
Eligibility:
*age
*asymptomatic
*pack-year history
*smoking status
*years since quit
Shared Decision-Making
*use of decision aids
*benefits & harms of screening
*follow-up diagnostic testing
*over-diagnosis
*false positive rate
*total radiation exposure
Counseling
*adherence to annual lung cancer LDCT screening
*impact of comorbidities
*ability or willingness to undergo diagnosis & treatment
Counseling
*maintain smoking abstinence
*smoking cessation
*furnish tobacco cessation interventions
Order for lung cancer screening with LDCT
CMS (2011)


Toolkit

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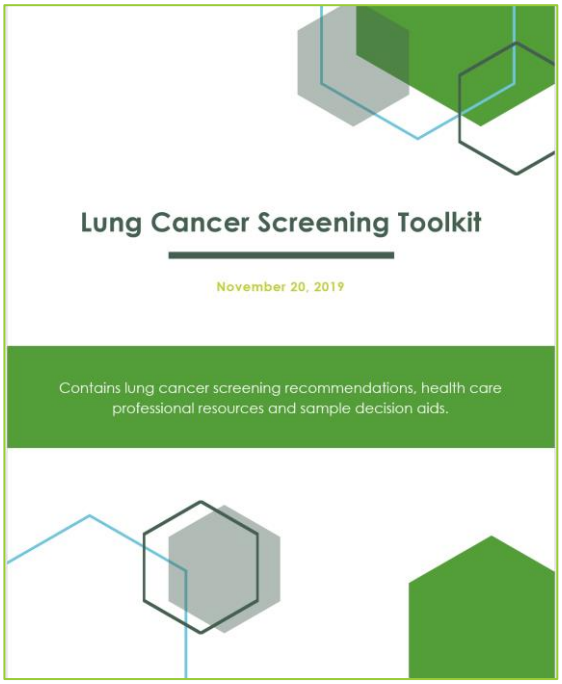
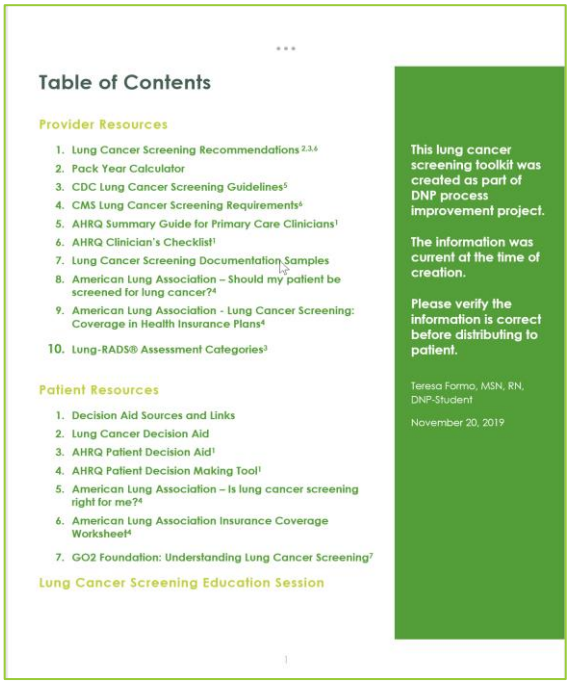
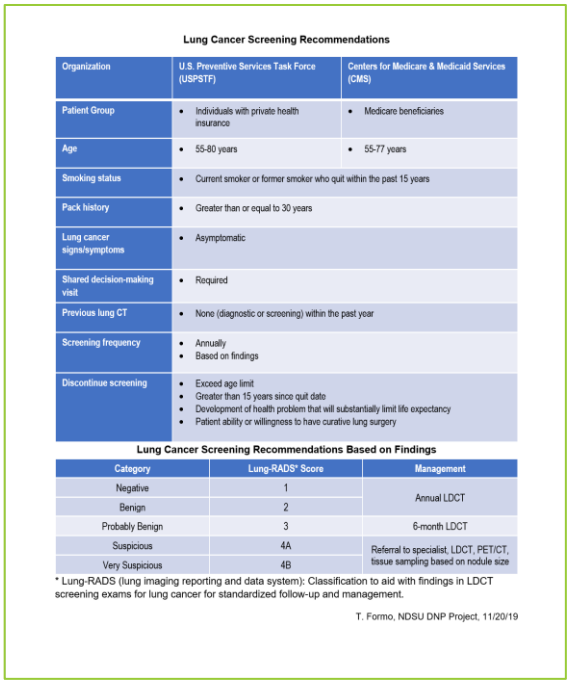
APPENDIX I. LUNG CANCER SCREENING TOOLKIT







Lung Cancer Screening Recommendations

Organization	U.S. Preventive Services Task Force (USPSTF)	Centers for Medicare & Medicaid Services (CMS)
Patient Group	• Individuals with private health insurance	• Medicare beneficiaries
Age	• 55-80 years	• 55-77 years
Smoking status	• Current smoker or former smoker who quit within the past 15 years	
Pack history	• Greater than or equal to 30 years	
Lung cancer signs/symptoms	• Asymptomatic	
Shared decision-making visit	• Required	
Previous lung CT	• None (diagnostic or screening) within the past year	
Screening frequency	• Annually • Based on findings	
Discontinue screening	• Exceed age limit • Greater than 15 years since quit date • Development of health problem that will substantially limit life expectancy • Patient ability or willingness to have curative lung surgery	

Lung Cancer Screening Recommendations Based on Findings

Category	Lung-RADS* Score	Management
Negative	1	Annual LDCT
Benign	2	
Probably Benign	3	6-month LDCT
Suspicious	4A	Referral to specialist, LDCT, PET/CT, tissue sampling based on nodule size
Very Suspicious	4B	

* Lung-RADS (lung imaging reporting and data system): Classification to aid with findings in LDCT screening exams for lung cancer for standardized follow-up and management.

T. Formo, NDSU DNP Project, 11/20/19

Resources:

American College of Radiology. (2019). *Lung-RADS® Version 1.1*. Retrieved from https://www.acr.org/-/media/ACR/Files/RADS/Lung-RADS/LungRADSAssessmentCategoriesv1-1.pdf

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LUNG CANCER SCREENING
PACK-YEAR CALCULATOR

YEARS SMOKED	Packs per day (20 cigarettes per pack)										
	0.5	1	1.5	2	2.5	3	3.5	4	4.5	5
5	2.5	5	7.5	10	12.5	15	17.5	20	22.5	25
6	3	6	9	12	15	18	21	24	27	30
7	3.5	7	10.5	14	17.5	21	24.5	28	31.5	35
8	4	8	12	16	20	24	28	32	36	40
9	4.5	9	13.5	18	22.5	27	31.5	36	40.5	45
10	5	10	15	20	25	30	35	40	45	50
11	5.5	11	16.5	22	27.5	33	38.5	44	49.5	55
12	6	12	18	24	30	36	42	48	54	60
13	6.5	13	19.5	26	32.5	39	45.5	52	58.5	65
14	7	14	21	28	35	42	49	56	63	70
15	7.5	15	22.5	30	37.5	45	52.5	60	67.5	75
16	8	16	24	32	40	48	56	64	72	80
17	8.5	17	25.5	34	42.5	51	59.5	68	76.5	85
18	9	18	27	36	45	54	63	72	81	90
19	9.5	19	28.5	38	47.5	57	66.5	76	85.5	95
20	10	20	30	40	50	60	70	80	90	100
21	10.5	21	31.5	42	52.5	63	73.5	84	94.5	105
22	11	22	33	44	55	66	77	88	99	110
23	11.5	23	34.5	46	57.5	69	80.5	92	103.5	115
24	12	24	36	48	60	72	84	96	108	120
25	12.5	25	37.5	50	62.5	75	87.5	100	112.5	125
26	13	26	29	52	65	78	91	104	117	130
27	13.5	27	40.5	54	67.5	81	94.5	108	121.5	135
28	14	28	42	56	70	84	98	112	126	140
29	14.5	29	43.5	58	72.5	87	101.5	116	130.5	145
30	15	30	45	60	75	90	105	120	135	150

Does *NOT meet criteria for screening*
Meets criteria for screening

Lung Cancer Screening Guidelines and Recommendations

Organization	Groups eligible for screening	Year
American Academy of Family Practice[1]	Evidence is insufficient to recommend for or against screening.	2013
American Association for Thoracic Surgery[2]	1. Age 55 to 79 years with ≥30 pack year[a] smoking history. 2. Long-term lung cancer survivors who have completed 4 years of surveillance without recurrence and who can tolerate lung cancer treatment following screening to detect second primary lung cancer until the age of 79. 3. Age 50 to 79 years with a 20 pack year smoking history and additional comorbidity that produces a cumulative risk of developing lung cancer ≥5% in 5 years.	2012
American Cancer Society[3]	Age 55 to 74 years in relatively good health with ≥30 pack year smoking history, who either currently smoke or have quit within the past 15 years; receive evidence-based smoking cessation counseling if they are current smokers; have undergone a process of informed/shared decision making that included information about the potential benefits, limitations, and harms of screening with low-dose CT; and have access to a high-volume, high-quality lung cancer screening and treatment center.	2019
American College of Chest Physicians[4]	Age 55 to 77 years, asymptomatic smokers and former smokers who have smoked 30 pack years or more and either continue to smoke or have quit within the past 15 years. *Asymptomatic* is defined as the absence of symptoms suggesting the presence of lung cancer.	2018
American Lung Association[5]	Age 55 to 77 years with ≥30 pack year smoking history and no history of lung cancer. Encourage CMS to extend age for screening coverage to match USPSTF age 55 to 80 years. Do not force patients to exit screening once they reach the 15-year mark of cessation. Do not exclude patients with chronic cough from screening. Provide screening for groups that were not incuded in the National Lung Screening Trial where biological plausibility exists for increase risk of lung cancer (e.g., from environmental exposure).Consider the use of risk prediction models.	2015
Centers for Medicare & Medicaid Services[6]	Age 55 to 77 years with ≥30 pack year smoking history and smoking cessation <15 years.	2015
National Comprehensive Cancer Network[7]	**Group 1:** Age 55 to77 years with ≥30 pack year smoking history and smoking cessation <15 years. **Group 2:** Age ≥50 years and ≥20 pack year smoking history and additional risk factors (other than secondhand smoke exposure) that increase the risk of lung cancer to >1.3% using Tammemagi lung cancer risk calculator.[b]	2019
U.S. Preventive Services Task Force[8]	Age 55 to 80 years with ≥30 pack year smoking history and smoking cessation <15 years (This recommendation is being updated).	2013

[a] *A pack year* is smoking an average of one pack of cigarettes per day for one year. For example, a person could have a 30 pack year history by smoking one pack a day for 30 years or two packs a day for 15 years.

[b] Additional risk factors include cancer history, lung disease history, family history of lung cancer, radon exposure, occupational exposure, and history of chronic obstructive pulmonary disease or pulmonary fibrosis. Cancers with increased risk of developing new primary lung cancer include survivors of lung cancer, lymphomas, cancer of the head and neck, and smoking-related cancers. Occupational exposures identified as carcinogens targeting the lungs include silica, cadmium, asbestos, arsenic, beryllium, chromium (VI), diesel fumes, and nickel.

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Reviewed: September 22, 2019 https://www.cdc.gov/cancer/lung/pdf/lung-cancer-screening-recommendations-508.pdf

CMS Lung Cancer Screening Requirements

Medicare beneficiaries considered high risk:

- Age 55 – 77 years old
- No current signs or symptoms of lung cancer
- At least a 30 pack-year history of tobacco smoking
- Current smoker or former smoker who quit within the past 15 years
- Written order for LDCT lung cancer screening

Documentation required as part of LDCT lung cancer screening order:

- Date of Birth
- Pack-year history of tobacco smoking
- Smoking status; if former smoker, the number of years since cessation
- Lack of signs and symptoms concerning for lung cancer
- The ordering provider's National Provider Identifier (NPI)

Beneficiary receives written order for LDCT lung cancer screening during a lung cancer screening counseling and shared decision-making visit provided by a physician or qualified non-physician practitioner (physician assistant, nurse practitioner, clinical nurse specialist). The following elements must be met and documented as part of shared decision-making:

- Determination of beneficiary eligibility for screening (age, lack of signs or symptoms of lung cancer, pack-year history of tobacco smoking, and number of years since quitting, if a former smoker).
- Shared decision-making using one or more decision aids; must include benefits and harms of screening, follow-up diagnostic testing, over-diagnosis, false positive rate, and total radiation exposure.
- Counseling to include the importance of adhering to annual lung cancer screening with LDCT, impact of comorbidities, and ability/willingness to be diagnosed and treated.
- Counseling for former smokers regarding the importance of sustaining tobacco smoking abstinence; and for current smokers the importance of smoking cessation. If appropriate, information is provided about smoking cessation interventions.
- When appropriate the provision of a written order for lung cancer screening with LDCT.

(Centers for Medicare and Medicaid Services, 2015)

https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274

Lung Cancer Screening: A Summary Guide for Primary Care Clinicians

Lung Cancer Screening With Low-Dose Computed Tomography (LDCT)

BACKGROUND

Primary care clinicians play a key role in determining the eligibility of patients for lung cancer screening, ensuring patients understand the benefits and harms of lung cancer screening, and working with patients to make decisions about screening that are consistent with the patients' values. Currently, annual screening with low-dose computed tomography (LDCT) is the only recommended screening strategy for lung cancer.

In 2012, lung cancer deaths accounted for about 27 percent of all cancer-related deaths in the United States. The median age at diagnosis was 70 years, and the number of new lung cancer cases was about 59 per 100,000 people. The median age at death was 72 years, and the number of deaths was 47 per 100,000 people. Although early detection and treatment is ideal, only 15 percent of lung cancer cases are diagnosed at an early stage. Smoking is the largest risk factor for lung cancer, causing about 85 percent of lung cancer cases in the United States.

OVERVIEW OF THE EVIDENCE

Published in August 2011, the National Lung Screening Trial (NLST) was the first trial to provide evidence to support screening for lung cancer with LDCT in reducing lung cancer deaths. The NLST randomized 53,454 high-risk individuals aged 55 to 74 years to three annual screenings with LDCT or standard chest x-rays and followed them for a median of 6.5 years. The study found that people were 16 to 20 percent less likely to die from lung cancer when screened with LDCT, as compared with standard screening chest x-rays. The mortality reduction is equivalent to three lung cancer deaths prevented per 1,000 people screened with three annual LDCT screens over 6.5 years. Previous studies had shown that screening with standard chest x-rays does not reduce the mortality rate from lung cancer. An overall reduction in mortality was also observed (about five in 1,000 fewer total deaths for individuals receiving LDCT rather than a chest x-ray).

Important harms of lung cancer screening with LDCT were also observed. These harms included a high number of false-positive scans and the low predictive value of a positive scan (only about 6 percent of positive scans led to a lung cancer diagnosis). Some people had invasive diagnostic procedures that led to major complications including infection, bleeding in the lung, or a collapsed lung. Radiation exposure from the LDCT screening and higher doses from followup diagnostic imaging studies were also concerns. The harms from cumulative radiation exposure—such as the rate of development of new cancer—are unknown. Concerns have also been raised about overdiagnosis. Data from the NLST trial suggests that 10 to 20 percent of lung carcinomas diagnosed by LDCT might have never been detected in the patient's lifetime in the absence of screening. Screening with LDCT also disclosed incidental findings (aortic aneurysms, coronary artery calcifications) and other lung findings (emphysema, bronchiectasis, pulmonary fibrosis, carcinoid tumors). However, the benefits of treating screening-detected findings other than lung cancer are unclear.

ELIGIBILITY CRITERIA FOR LUNG CANCER SCREENING

Criteria according to:	USPSTF	CMS[a]
Relevant group:	Persons with private health insurance	Medicare beneficiaries
Age (years):	55–80	55–77
Smoking status:	Current or former[b] smoker	
Smoking history:	30 pack-years[c]	
Lung cancer signs:	Asymptomatic (no signs of lung cancer)	
Screening frequency:	Yearly	
When to stop screening:	The patient exceeds upper age criterion, has not smoked for more than 15 years, and/or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative surgery	

CMS = Centers for Medicare & Medicaid Services; USPSTF = U.S. Preventive Services Task Force

[a] CMS requires that the beneficiary receive a written order for LDCT by a physician or nonphysician practitioner, as outlined in CMS policies for initial or subsequent LDCT lung cancer screening.

[b] Former smokers must have quit within the last 15 years.

[c] (Number of pack-years = (Average number of packs smoked per day) X (Years smoked)) Note there are 20 cigarettes in 1 pack.

INSURANCE COVERAGE

Both private insurers and Medicare offer coverage for annual LDCT screening for lung cancer among eligible high-risk individuals who meet all the eligibility criteria. (See Eligibility Criteria For Lung Cancer Screening table.) Private insurance plans and Medicare cover lung cancer screening with no out-of-pocket costs.

Followup invasive diagnostic procedures and repeat imaging to evaluate an abnormal screening test may require out-of-pocket costs.

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

SUMMARY OF THE EVIDENCE FROM THE NATIONAL LUNG SCREENING TRIAL*

Benefits: How did LDCT scans compare with chest x-rays in reducing deaths from lung cancer per 1,000 people screened?

	LDCT	Chest x-ray	
Deaths from lung cancer over 6.5-year followup period	18 in 1,000	21 in 1,000	3 in 1,000 fewer deaths from lung cancer with LDCT
Deaths from all causes over 6.5-year followup period	70 in 1,000	75 in 1,000	5 in 1,000 fewer deaths from all causes with LDCT

*About the NLST: more than 50,000 smokers participated; participants had up to three annual screenings; average followup was 6.5 years.

Harms: What are the harms of screening for lung cancer with LDCT?

	Of 1,000 people screened
Positive (abnormal) results	380
False positives ("false alarms")	356 (about 94%)
Invasive diagnostic procedures (among people with a false positive result)	18
Major complications from invasive diagnostic procedures (e.g., infection, bleeding in lung, collapsed lung)	0.4
Overdiagnosis (diagnosed lung cancer that never would have progressed to cause the patient harm)	
» Estimated at 10–20 percent of lung cancer cases diagnosed with LDCT.	
Radiation exposure (from screening and diagnostic imaging, including cumulative exposure)	
» Harms of repeated exposure to radiation from LDCT and diagnostic imaging, such as causing new cancer, are unknown.	
Comparing sources of radiation exposure with a single LDCT scan:	
Air travel, 10 hours	0.04 mSv
Chest x-ray	0.1 mSv
Screening mammogram	0.4 mSv
LDCT scan	1.4 mSv
Average background radiation in the United States (1 year)	3.0–5.0 mSv
Diagnostic CT	7.0 mSv

mSv = millisievert, a measure of the amount of radiation absorbed by the body

SMOKING CESSATION RESOURCES

BeTobaccoFree.gov (U.S. Department of Health and Human Services)
tinyurl.com/ap657cz
Smoking Quitline: 1-877-448-7848

Smoking & Tobacco Use (Centers for Disease Control and Prevention)
tinyurl.com/yu5jfvf
Smoking Quitline: 1-800-784-8669

Help for Smokers and Other Tobacco Users (Agency for Healthcare Research and Quality)
tinyurl.com/owj68h4

Smokefree.gov (U.S. Department of Health and Human Services)
smokefree.gov/ready-to-quit

BENEFICIARY REQUIREMENTS FROM CMS

Initial LDCT Lung Cancer Screening Service: The beneficiary must receive a written order for LDCT screening during a lung cancer screening counseling and shared decisionmaking visit with a physician or qualified nonphysician practitioner. The initial screening visit must meet the following criteria and must be appropriately documented in the beneficiary's medical record to be covered by Medicare.

- Must be a shared decisionmaking visit, use one or more decision aids, and include discussion of the potential benefits and harms of screening, such as the possibility of followup diagnostic testing, the risk of overdiagnosis, the false-positive rate, and total radiation exposure.

  Shared decisionmaking is a communication process in which practitioners discuss options and work collaboratively with patients toward preference-based decisions.
- Must include counseling on the importance of adherence to annual lung cancer LDCT screening, the impact of comorbidities on the likelihood of being able to benefit from screening due to the ability to undergo treatment, and willingness to undergo diagnosis and treatment.
- Must include counseling on the importance of not smoking for current and former smokers, and must provide information on tobacco cessation interventions.

Subsequent LDCT Lung Cancer Screening Service: Although not required, a physician or qualified nonphysician practitioner may choose to provide a counseling and shared decisionmaking visit for subsequent screenings. The components of the visit are the same as those for the initial visit.

- The patient must receive a written order for LDCT screening during any visit.

Written orders for both initial and subsequent LDCT lung cancer screenings must contain the following information and be appropriately documented in the beneficiary's medical record:

- 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

To locate accredited imaging facilities go to *www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilities/Lung-Cancer-Screening-Registries.html.*

POINTS TO DISCUSS WITH YOUR PATIENTS

- LDCT is the only recommended screening approach for lung cancer.
- Screening is not a substitute for quitting smoking. The most important way to lower the chance of dying from lung cancer is to stop smoking.
- Screening should be done annually until the patient no longer needs to be screened or no longer meets the screening criteria.
- Screening is a process. An abnormal LDCT scan does not necessarily mean cancer. Additional testing may be needed to determine a diagnosis.
- Review the evidence about the benefits and harms of screening with your patients.

AHRQ

AHRQ Publication No. 16-EHC007-10
March 2016

Lung Cancer Screening: A Clinician's Checklist

This checklist was developed to help clinicians meet the Centers for Medicare & Medicaid Services (CMS) criteria for a lung cancer screening counseling and shared decisionmaking visit. All of the criteria listed below must be met for the screening to be covered as a preventive service benefit under Medicare.

Before...

The Clinical Encounter

Determine patient's eligibility.
This checklist may be completed with the assistance of a nurse, physician assistant, or other medical assistant.

» Is the patient 55 to 77 years old? (55 to 80 years old for patients with private insurance)	☐ Yes	☐ No[a]
» Is the patient a current smoker or former smoker who has quit within the past 15 years?	☐ Yes	☐ No[a]
» Does the patient have at least a 30 pack-year smoking history? (See the calculator below.)	☐ Yes	☐ No[a]
» Is the patient asymptomatic for lung cancer with no personal history of lung cancer?	☐ Yes	☐ No[a,b]
» Is the patient healthy enough to have lung surgery?	☐ Yes	☐ No[a]
» Is the patient willing to receive potentially curative treatment?	☐ Yes	☐ No[a]

Calculate Pack-Years

(20 cigarettes = 1 pack)

Number of years smoked	×	Average number of packs smoked per day	=	Pack-years
	×		=	

During...

The Clinical Encounter

Complete all of the following activities.

- ☐ **Documented all elements in the patient's medical chart.**
  - » Used a decision aid
- ☐ **Discussed potential benefits of lung cancer screening:**
  - » Reduced mortality from lung cancer
- ☐ **Discussed potential harms of lung cancer screening, including:**
  - » False-positive results
  - » Followup testing if an abnormality is found (and the possible complications of invasive testing)
  - » Overdiagnosis
  - » Total radiation exposure (screening and diagnostic testing, cumulative)
- ☐ **Discussed other issues:**
  - » The impact of comorbidities on screening (the benefit of screening is reduced in patients with poor health)
  - » The patient's ability or willingness to undergo invasive diagnostic procedures and treatment
- ☐ **Counseled about:**
  - » The importance of adherence to annual lung cancer screening
  - » The importance of maintaining cigarette smoking abstinence or smoking cessation, as applicable
  - » Tobacco cessation interventions (provided information, if appropriate)

After...

The Clinical Encounter

- ☐ **Establish the next steps.**
  If the patient would like screening, provide a written order for the lung cancer screening visit with the following elements:
  - » Patient's date of birth
  - » Actual pack-year smoking history
  - » Current smoking status; for former smokers, the number of years since quitting
  - » Statement that the patient is asymptomatic
  - » National Provider Identifier (NPI) of the ordering practitioner
- » If the patient declines screening, document the discussion and the patient's decision in his or her medical record.
- » If the patient is unsure about screening or wants more time, consider scheduling a followup visit to discuss the patient's screening decision.
- » For all patients, reinforce the importance of smoking cessation and abstinence.

[a] Screening is not recommended. If the patient is a current smoker, encourage smoking cessation and provide resources. If the patient is a former smoker, encourage continued abstinence and provide additional support if needed.

[b] Symptomatic patients may need followup and diagnostic testing, but not screening. Patients with a history of lung cancer need surveillance, but not screening.

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The importance of shared decisionmaking

Lung cancer screening with low-dose computed tomography (LDCT) reduces mortality from lung cancer. There are also potential harms associated with lung cancer screening, including a high-false positive rate and the associated need for diagnostic followup, known and unknown risks of additional testing associated with incidental findings, cumulative radiation exposure, and overdiagnosis. Shared decisionmaking is a collaborative patient-centered process in which patients and clinicians make decisions together, within the context of the best evidence and recommendations and based on the patient's values and preferences.

Tips To Promote a Shared Decision

Below is a five-step process for shared decisionmaking that includes exploring and comparing the possible benefits and harms of each option through meaningful dialogue about what matters most to the patient.

- **STEP 1:** Seek your patient's participation in the decisionmaking process.
- **STEP 2:** Help your patient explore and compare the potential benefits and harms of lung cancer screening, and assess your patient's level of understanding. (See the teach-back examples in the box to the far right.)
- **STEP 3:** Assess your patient's values and preferences about lung cancer screening.
- **STEP 4:** Reach a decision about lung cancer screening with your patient.
- **STEP 5:** Evaluate your patient's feelings about the decision by having a followup discussion.

Ordering Information

Lung Cancer Screening with Low-Dose Computed Tomography (LDCT): Tools for Primary Care Clinicians, is a free multicomponent resource to support decisionmaking about lung cancer screening in the primary care setting. For electronic copies of this multicomponent resource, visit *www.effectivehealthcare.ahrq.gov/LCS/*

Talking Points

Below are specific points to address during the clinical encounter.

- » Lung cancer screening can be effective if patients 1) follow the screening protocol, 2) undergo diagnostic followup procedures after a positive screening result, and 3) receive treatment, which has potential harms.
- » Screening does not mean that smoking is OK. Smoking still causes lung cancer, cardiovascular disease, and other lung disease.
- » Screening can lead to early treatment that can prevent some, but not all, lung cancer deaths.
- » False-positive results ("false alarms") are common, and additional scans or invasive procedures may be needed. Less commonly, major complications of invasive procedures can occur, including bleeding, infection, or a collapsed lung.
- » Lung cancer screening may find lung cancer that would not have ever caused symptoms or harmed the patient in his or her lifetime if the cancer had not been found. This could lead to treatment of people who do not really need treatment.
- » Screening and followup testing exposes patients to radiation. The harms associated with cumulative radiation exposure are unknown.
- » Screening should stop if the patient 1) exceeds the upper age criterion, 2) no longer wants screening, 3) has a worsening health condition that limits their life expectancy or increases the risk of complications from lung surgery, or 4) has not smoked for 15 years.

Teach-Back Examples

"I know I have given you a lot of information. Tell me in your own words what you have heard."

"What are your thoughts about lung cancer screening?"

"Let's stop right there for a moment. What questions or comments do you have about the information I have given you?"

Referral Information

To find a radiology imaging facility that meets the CMS eligibility criteria, please visit:

www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/Lung-Cancer-Screening-Registries.html

AHRQ

AHRQ Publication No. 16-EHC007-11
March 2016

LUNG CANCER SCREENING DOCUMENTATION SAMPLES

OPTION 1:

Nancy 67, DOB June 12, 1952, is a current / former smoker with a 42-pack year smoking history. The patient quit smoking _____ years ago. Nancy is asymptomatic for lung cancer, has no history of lung cancer and has not a lung CT within the past 12 months.

During this visit, I counseled Nancy on lung cancer screening with the use of a decision aid to guide our shared decision-making process.

Nancy was counseled on the potential harms and benefits of lung cancer screening including false positives, radiation exposure, and overdiagnosis. The patient is aware of the possible results of a screening CT for lung cancer.

- Positive findings: Nancy knows that LDCT screening does not diagnose lung cancer and additional diagnostic tests, or procedures may by required.
- Negative findings: Nancy knows that a negative scan means that the risk of cancer at the time of screening is low, but not zero.

Nancy is aware of the importance of adherence to annual LDCT until the age of 77, or if another health problem supersedes lung cancer screening. The patient understands that she should only undergo lung cancer screening if she is able and willing to undergo lung cancer treatment, including surgery.

Order placed for CT Chest Screen.

OPTION 2:

Nancy is a 67-year old with a smoking history of 42 pack years. Nancy is a current / former smoker. (She quit smoking 8 years ago). She has no history of lung cancer, no symptoms of possible lung cancer, a reasonable life expectance, and is willing to consider lung surgery if recommended.

Benefits and harms of annual screening with LDCT scans were discussed. Benefits include mortality reduction. Possible harms include radiation exposure of CT scans, over-diagnosis, false positive results leading to additional testing including invasive procedures, and major complications of those procedures.

The patient was counseled on the importance of adhering to annual LDCT until age 77, or until co-morbidities surpass lung cancer screening. Nancy was counseled on the importance of smoking cessation / maintaining smoking cessation. Nancy did / did not plan to quit smoking. Smoking cessation information provided.

Decision to proceed with annual CT scans for lung cancer screening. A lung cancer decision aid was used in this shared decision-making discussion about LDCT for lung cancer screening.

OPTION 3:

I have used a decision aid in the shared decision making with Nancy about interventions to reduce the risk of dying from lung cancer, including quitting smoking and annual lung cancer screening. The patient is eligible for screening based on age (67), smoking history (42 pack years), and the absence of signs or symptoms of lung cancer.

We discussed the potential harms of screening, including false positives, follow-up diagnostic testing, overtreatment and total radiation exposure. The patient was counseled on the importance of adherence to annual LDCT screening, the impact of comorbidities, and the ability/willingness to undergo diagnosis and treatment of screening findings.

The patient was counseled on the importance of smoking cessation and offered smoking cessation resources. The patient had decided not to quit smoking.
OR
The patient was counseled on the importance of smoking cessation and offered smoking cessation resources. The patient has decided to quit smoking. Referred to SD Quitline (1.866.SD.QUITS). Prescriptions supplied:
OR
The patient was counseled on the importance of maintaining smoking cessation in lung cancer prevention. After considering the risk and benefits of lung cancer screening for Nancy, she has decided to get screened.

Order for screening place.

OPTION 4:

I have discussed and reviewed with Nancy eligibility for Lung Cancer Screening during this office visit. The following were discussed with the patient:

Patient is within the age range for screening. **YES / NO**

Patient is a former smoker with a smoking history of ___ pack per day for ___years and quit _____ years ago.
OR
Patient is a current smoker with a smoking history of _1 pack per day for _42 years.

I discussed benefits and harms of screening, follow-up diagnostic testing and procedures, overdiagnosis, false positive rate and total radiation exposure. **DONE / NOT DONE**

Patient was counseled on the importance of adherence to annual lung cancer LDCT screening, impact of co-morbidities, and ability or willingness to undergo diagnosis and treatment. **DONE / NOT DONE**

Patient was counseled on the importance of maintaining cigarette smoking abstinence (former smoker). **DONE / NOT DONE**
OR
Patient was counseled on the importance of smoking cessation (current smoker). **DONE / NOT DONE**

Tobacco cessation interventions provided. **DONE / NOT DONE**

Current lung cancer symptoms present: (must be asymptomatic to qualify for lung cancer screening with LDCT)

- None - asymptomatic
- Persistent cough
- Hemoptysis
- Dyspnea
- Hoarseness
- Fatigue that doesn't resolve
- Pneumonia
- Pain with swallowing
- Chest pain

An order has been placed for the patient. **YES / NO**

T. Formo, MSN, RN, DNP-Student
NDSU DNP Project, 11/20/19

AMERICAN LUNG ASSOCIATION.

Should my patient be screened for lung cancer?

Screening is a test used to detect lung cancer before any symptoms appear. Screening with low-dose CT (LDCT) scans can reduce deaths in those at high risk. Below are key points you may want to use in discussion with your patients who may be at risk for lung cancer or are worried about their risk for lung cancer.

Remember: The best way to prevent lung cancer is to never smoke or stop smoking now. If your patients are still smoking, talk to them about ways you can help them quit. Visit Lung.org/stop-smoking for helpful resources.

Q: Who is a good candidate for lung cancer screening?

A: If a patient meets the following criteria, they are considered to be at "high risk" for developing lung cancer and screening is recommended:

- 55-80 years of age
- Have a 30 pack-year history of smoking (this means 1 pack a day for 30 years, 2 packs a day for 15 years, etc.)
- AND, are a current smoker, or have quit within the last 15 years

There is insufficient evidence at this time that other groups benefit from screening, however your clinical judgment is always relevant.

A note on insurance coverage:

Many, but not all, private insurance plans will cover lung cancer screening for individuals who meet the high risk criteria above without cost-sharing, and Medicare will cover screening for individuals 55-77 who meet the high risk criteria. However, health plans may require prior authorization or charge patients if the facility or provider is "out of network.

Be sure to advise your patient to check with their insurance plan for screening coverage and for any additional procedures—there may be other costs associated even if the actual screening is free and to ask for any cost estimates in writing.. Ask the referral facility doing the LDCT scan to carefully and clearly explain to your patient all the costs that they may incur and not just the cost of the LDCT scan alone. Recommend your patients use the Lung Cancer Screening Insurance Checklist as guidance.

1-800-LUNGUSA | SavedByTheScan.org

AMERICAN LUNG ASSOCIATION.

Q: What should I discuss with my patient who may be a candidate for lung cancer screening?

A: Low-dose CT scan screening is a complicated process and a discussion with any patient should include the activities below. Review these requirements when considering LDCT screening for a patient.

- Take a complete health history
- Determine possible comorbidities
- Discuss the benefits and risks and possible additional procedures that may happen after LDCT screening
- Discuss the costs of screening, including financial, personal and time costs
- Advise current smokers to quit smoking, offering to help them with appropriate pharmacologic and behavioral options

* Chest X-rays rays should never be used for lung cancer screening.

Q: Where should I refer a patient for an LDCT scan to screen for lung cancer?

A: Refer them to institutions that have experience in conducting low-dose CT scans

- A facility using the latest technology for lung cancer screening
- An expert multidisciplinary team that can provide follow-up for evaluation of nodules. (If the facility does not have that expertise on site, they should be able to make referrals to appropriate institutions.)

Please note, Medicare has a specific protocol in place for physicians and screening institutions. Review these requirements when considering LDCT screening for a patient on Medicare.

Q: What do the results mean?

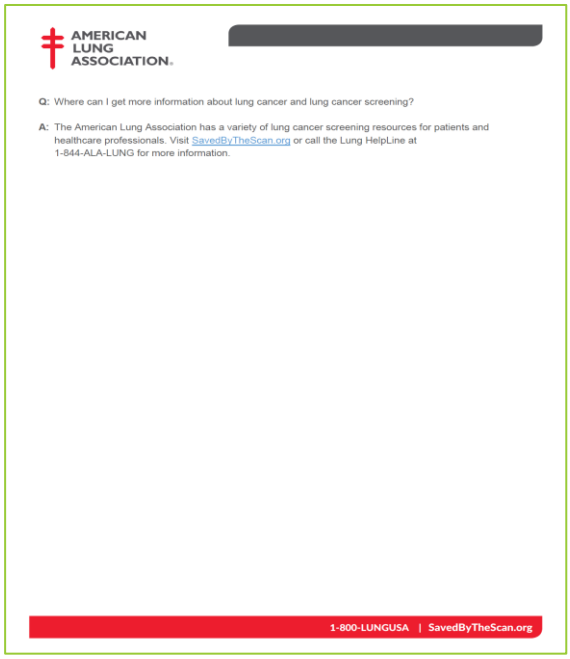
A: A "positive" result means that the low-dose CT scan shows something abnormal. This is usually a nodule of a concerning size. Your patient may need to have additional scans or other procedures to find out exactly what it is. You and the team of experts should discuss all possible treatment options with the patient, including clinical trials.

A "negative" result means there were no abnormal findings at this time on this scan. You should discuss when and if your patient should be tested again.

There may also be an "indeterminate" result and you and the expert team will recommend watchful follow-up and further imaging at a later time.

Whatever the result, if your patient is still smoking, talk to them about ways to help them quit.

1-800-LUNGUSA | SavedByTheScan.org



AMERICAN LUNG ASSOCIATION.

Q: Where can I get more information about lung cancer and lung cancer screening?

A: The American Lung Association has a variety of lung cancer screening resources for patients and healthcare professionals. Visit SavedByTheScan.org or call the Lung HelpLine at 1-844-ALA-LUNG for more information.

1-800-LUNGUSA | SavedByTheScan.org

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Lung Cancer Screening: Coverage in Health Insurance Plans

The 2011 National Lung Screening Trial (NLST) found screening individuals at high risk for lung cancer could reduce mortality from the nation's leading cancer killer by as much as 20 percent. Subsequently, the U.S. Preventive Services Task Force gave lung cancer screening a 'B' recommendation, and Medicare also added coverage of screening for individuals at high risk. Below is an explanation of how screening is covered for various types of insurance.

Plan/Type of Plan	Population Served by Plan	Requirement for Coverage of Lung Cancer Screening (Must meet ALL criteria)	Cost-Sharing Allowed?
Medicare's National Coverage Determination			
Traditional Medicare	Ages 65+	Coverage implemented in Medicare Part B for ages 55-77. No signs or symptoms of lung cancer 30 pack-years smoking history Current smoker or quit smoking in the last 15 years	No, patients should not be charged a copay, coinsurance, or deductible for screening. However, patients must go to a Medicare-approved facility and provider to avoid extra costs.
Medicare Advantage (MA)	Ages 65+ who opt for Medicare Advantage plans	Coverage required for ages 55-77. MA plans may opt to cover screening for individuals 78 and older. No signs or symptoms of lung cancer 30 pack-years smoking history Current smoker or quit smoking in the last 15 years	No, patients should not be charged a copay, coinsurance, or deductible for screening. However, patients may need to go to an "in network" facility and provider to avoid extra costs.
U.S. Preventive Services Task Force (USPSTF) Recommendation**			
Medicaid Expansion	Incomes up to 138% of the Federal Poverty Level (in states that have chosen to expand Medicaid), including childless adults	Age 55-80 30 pack-years smoking history Current smoker or quit smoking in the last 15 years	No, patients should not be charged a copay or other costs for screening. However, patients should check if there are certain facilities or providers they must use for the screening to avoid extra costs.
State Health Insurance Marketplace Plans	Mostly the unemployed, self-employed, part-time workers, and employees of small companies. Individuals and families who make up to 400% of the Federal Poverty Level are eligible for subsidies	Age 55-80 30 pack-years smoking history Current smoker or quit smoking in the last 15 years	No, patients should not be charged a copay, coinsurance, or deductible for screening. However, patients may need to go to an "in network" facility and provider to avoid extra costs.

Large Group and Self-Insured Plans*	Employees of large employers (over 50 employees), member of unions	Age 55-80 30 pack-years smoking history Current smoker or quit smoking in the last 15 years	No, patients should not be charged a copay, coinsurance, or deductible for screening. However, patients may need to go to an "in network" facility and provider to avoid extra costs.
Other			
Traditional Medicaid	Lowest income individuals, mostly children, pregnant women and disabled	No automatic requirement. Coverage set by state policymakers.	Yes
Small Group and Individual Plans (Outside Marketplaces)*	Mostly the unemployed, self-employed, part-time workers, and employees of small companies.	Many plans must comply with the USPSTF standard mentioned above. However, certain plans – like short-term limited-duration plans, association health plans and plans sold directly by farm bureaus or health ministries – do not have to follow these standards and may not cover lung cancer screening.	Varies.

* Grandfathered plans are not required to cover preventive services without cost-sharing.
** The U.S. Preventive Services Task Force (USPSTF) issued a new 'B' recommendation for lung cancer screenings on December 30, 2013 for those at high risk. Under the Affordable Care Act, most plans must cover preventive services given an 'A' or 'B' by the USPSTF.

Updated 10/29/2019.

Lung-RADS® Version 1.1

Assessment Categories Release date: 2019

Category Descriptor	Lung-RADS Score	Findings	Management	Risk of Malignancy	Est. Population Prevalence
Incomplete	0	Prior chest CT examination(s) being located for comparison Part or all of lungs cannot be evaluated	Additional lung cancer screening CT images and/or comparison to prior chest CT examinations is needed	n/a	1%
Negative No nodules and definitely benign nodules	1	No lung nodules Nodule(s) with specific calcifications: complete, central, popcorn, concentric rings and fat containing nodules	Continue annual screening with LDCT in 12 months	< 1%	90%
Benign Appearance or Behavior Nodules with a very low likelihood of becoming a clinically active cancer due to size or lack of growth	2	**Perifissural nodule(s)** *(See Footnote 11)* < 10 mm (524 mm³) **Solid nodule(s):** < 6 mm (< 113 mm³) new < 4 mm (< 34 mm³) **Part solid nodule(s):** < 6 mm total diameter (< 113 mm³) on baseline screening **Non solid nodule(s) (GGN):** <30 mm (<14137 mm³) **OR** ≥ 30 mm (≥ 14137 mm³) and unchanged or slowly growing **Category 3 or 4 nodules unchanged for ≥ 3 months**			
Probably Benign Probably benign finding(s) - short term follow up suggested; includes nodules with a low likelihood of becoming a clinically active cancer	3	**Solid nodule(s):** ≥ 6 to < 8 mm (≥ 113 to < 268 mm³) at baseline **OR** new 4 mm to < 8 mm (34 to < 113 mm³) **Part solid nodule(s)** ≥ 6 mm total diameter (≥ 113 mm³) with solid component < 6 mm (< 113 mm³) **OR** new < 6 mm total diameter (< 113 mm³) **Non solid nodule(s)** (GGN) ≥ 30 mm (≥ 14137 mm³) on baseline CT or new	6 month LDCT	1-2%	5%
Suspicious Findings for which additional diagnostic testing is recommended	4A	**Solid nodule(s):** ≥ 8 to < 15 mm (≥ 268 to < 1767 mm³) at baseline **OR** growing < 8 mm (< 268 mm³) **OR** new 6 to < 8 mm (113 to < 268 mm³) **Part solid nodule(s):** ≥ 6 mm (≥ 113 mm³) with solid component ≥ 6 mm to < 8 mm (≥ 113 to < 268 mm³) **OR** with a new or growing < 4 mm (< 34 mm³) solid component **Endobronchial nodule**	3 month LDCT; PET/CT may be used when there is a ≥ 8 mm (≥ 268 mm³) solid component	5-15%	2%
Very Suspicious Findings for which additional diagnostic testing and/or tissue sampling is recommended	4B	**Solid nodule(s)** ≥ 15 mm (≥ 1767 mm³) **OR** new or growing, and ≥ 8 mm (≥ 268 mm³) **Part solid nodule(s) with:** a solid component ≥ 8 mm (≥ 268 mm³) **OR** a new or growing ≥ 4 mm (≥ 34 mm³) solid component	Chest CT with or without contrast, PET/CT and/or tissue sampling depending on the "probability of malignancy and comorbidities. PET/CT may be used when there is a ≥ 8 mm (≥ 268 mm³) solid component. *For new large nodules that develop on an annual repeat screening CT, a 1 month LDCT may be recommended to address potentially infectious or inflammatory conditions*	> 15%	2%
	4X	Category 3 or 4 nodules with additional features or imaging findings that increases the suspicion of malignancy			
Other Clinically Significant or Potentially Clinically Significant Findings (non lung cancer)	S	**Modifier - may add on to category 0-4 coding**	As appropriate to the specific finding	n/a	10%

IMPORTANT NOTES FOR USE:

1) Negative screen: does not mean that an individual does not have lung cancer
2) Size: To calculate nodule mean diameter, measure both the long and short axis to one decimal point, and report mean nodule diameter to one decimal point
3) Size Thresholds: apply to nodules at first detection, and that grow and reach a higher size category
4) Growth: an increase in size of > 1.5 mm (> 2 mm³)
5) Exam Category: each exam should be coded 0-4 based on the nodule(s) with the highest degree of suspicion
6) Exam Modifiers: S modifier may be added to the 0-4 category
7) Lung Cancer Diagnosis: Once a patient is diagnosed with lung cancer, further management (including additional imaging such as PET/CT) may be performed for purposes of lung cancer staging; this is no longer screening
8) Practice audit definitions: a negative screen is defined as categories 1 and 2, a positive screen is defined as categories 3 and 4
9) Category 4B Management: this is predicated on the probability of malignancy based on patient evaluation, patient preference and risk of malignancy, radiologists are encouraged to use the McWilliams et al assessment tool when making recommendations
10) Category 4X: nodules with additional imaging findings that increase the suspicion of lung cancer, such as spiculation, GGN that doubles in size in 1 year, enlarged lymph nodes etc
11) Solid nodules with smooth margins, an oval, lentiform or triangular shape, and maximum diameter less than 10 mm or 524 mm³ (perifissural nodules) should be classified as category 2
12) Category 3 and 4A nodules that are unchanged on interval CT should be coded as category 2, and individuals returned to screening in 12 months
13) LDCT: low dose chest CT

**Additional resources available at - https://www.acr.org/Clinical-Resources/Reporting-and-Data-Systems/Lung-Rads*

**Link to Lung-RADS calculator - https://brocku.ca/lung-cancer-screening-and-risk-prediction/risk-calculators/*

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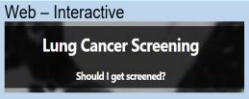
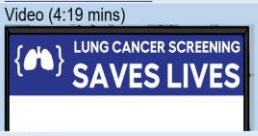
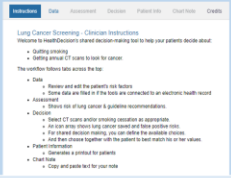
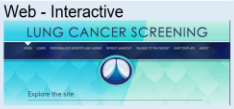
Decision Aid	Source	Media	Personal Risk Assessment	Link
SHOULD I SCREEN	University of Michigan	Web – Interactive 	Yes	https://shouldiscreen.com/
UNDERSTANDING LUNG CANCER SCREENING	GO2 Foundation for Lung Cancer	Web – Interactive and Print 	No	https://go2foundation.org/for-professionals/
SCREENING SAVES LIVES	GO2 Foundation for Lung Cancer	Video (4:19 mins) 	No	https://vimeo.com/353423836
LCS WITH COMPUTERIZED TOMOGRAPHY (CT)	American Thoracic Society	Print 	No	https://www.thoracic.org/patients/patient-resources/resources/decision-aid-lcs.pdf
LCS TOOLS FOR PATIENTS & CLINICIANS	Agency for Healthcare Research and Quality	Web – Interactive and Print 	No	https://effectivehealthcare.ahrq.gov/decision-aids/lung-cancer-screening/home.html

Decision Aid	Source	Media	Personal Risk Assessment	Link
LCS SAVES LIVES	American Lung Association	Web – Interactive and Print 	No	http://www.savedbythescan.org/
LCS BENEFITS, HARMS OF CHEST CT SCANS	Health Decision	Web – Interactive 	Yes	https://www.healthdecision.org/tool.html#/tool/lungca
LCS	Center for Clinical Management research, Ann Arbor VHA	Web - Interactive  Generates printable information and EMR note	Yes	https://lungdecisionprecision.com/
LUNG CANCER PROJECT	Genetech	Web – Interactive 	No	https://www.thelungcancerproject.org/screening/
LUNG CANCER	CDC	Web – Interactive	No	https://www.cdc.gov/cancer/lung/health-care-providers/index.htm

T. Formo, MSN, RN, DNP-Student
NDSU DNP Project
11/20/19

Lung Cancer Screening Decision Aid

Lung Cancer is:

- The leading cause of cancer death in the United States. Every year 150,000 people die from lung cancer.
- The 3rd most common cancer in the United States. Every year about 220,000 people are diagnosed with lung cancer.
- About 9 out of every 10 people with lung cancer die because it is often diagnosed once it has spread outside the lungs.
- Curable with surgery when found early.

Lung Cancer Screening

- Test used to find early-stage lung cancer when it is easier to treat and more likely to be cured.
- Looks for early lung cancer wth a CT scan using a low dose of radiation. This is called a low-dose computed tomography or LDCT.
- Screening with LDCT reduced the number of deaths by 20% in those at high risk when compared to screening with chest x-ray.
- May find other conditions or diseases that need to be treated.
- Lung cancer can spread quickly. Screening is recommended every year to identify changes.

Consider Screening if:

- You are 55-77 years old.
- You are a current smoker or former smoker who quit less than 15 years ago.
- You are or have a history of smoking at least 30-pack years (heavy smoker).

Calculating Pack-Years

- 1 pack = 20 cigarettes
- Pack years calculated by multiplying average number of packs smoked per day X number of years smoked.
- Example: 1 pack per day smoked for 30 years = 30 pack-years.
  1 ½ packs per day smoked for 15 years = 30 pack-years

Screening is Not Recommended if:

- You are younger than 55 or older than 80 (77 for Medicare patients)
- You smoked less than 30-pack years or quit more than 15 years ago.
- You have a condition that limits how long you may live.
- You are not willing or able to have surgery for lung cancer.
- You are not willing to be screened every year you are eligible.
- You already have symptoms of lung cancer (cough, chest pain, hoarse voice, unexplained weight loss, loss of appetite, coughing up blood, shortness of breath, wheezing). Inform your health care professional.

Harms of Screening:

- Some cancers may still be missed.
- False Positives are spots found in lungs during screening that are not cancers.
- Additional scans or procedures may be needed to diagnose or rule out cancer.
- Anxiety and stress waiting for results and additional testing.
- Exposure to radiation. The LDCT scan uses 75% less radiation than a regular CT.
- Overdiagnosis or treatment for a cancer that would not have caused any problems.

Understanding the Results:

- Positive: the scan shows something abnormal.
  - You may need to have additional scans or other procedures for diagnosis.
- Negative: there were no abnormal findings on the scan at this time.

Insurance Coverage

- Private insurance covers screening for ages 55 through 80.
- Medicare covers screening for people ages 55 up to 77.
- Additional costs for follow-up tests and/or treatments after the initial screen. Contact insurance company to see if procedures are covered.

Reduce Lung Cancer Risk

- Stop smoking or never start smoking
- Call SD Quitline for help with smoking cessation:
  - 1.866.SD-QUITS (1.866.737.8487)
- Avoid exposure to secondhand smoke, radon, and hazardous materials in the workplace and home.

Resources

- American Cancer Society https://www.cancer.org/latest-news/who-should-be-screened-for-lung-cancer.html
- American Lung Association https://www.lung.org/our-initiatives/saved-by-the-scan/
- Go2Foundation https://go2foundation.org/
- AHRQ https://effectivehealthcare.ahrq.gov/decision-aids/lung-cancer-screening/patient.html

T. Formo, MSN, RN, DNP-Student
NDSU DNP Project
11/20/19

Is Lung Cancer Screening Right for Me?

A decision aid for people considering lung cancer screening with low-dose computed tomography

If you have smoked for many years, you may want to think about screening (testing) for lung cancer with low-dose computed tomography (LDCT). Before deciding, you should think about the possible benefits and harms of lung cancer screening. This decision aid will help prepare you to talk with your health care professional about whether lung cancer screening is right for you.

What are the facts about lung cancer?

- Lung cancer is the leading cause of cancer death in the United States. Each year, about 220,000 people are diagnosed with lung cancer and 150,000 people die from lung cancer.
- About half of the people diagnosed with lung cancer are 70 years of age or older. The typical age of death from lung cancer is 72 years.

What is lung cancer?

Lung cancer happens when abnormal cells form in the lungs and grow out of control. These cells can form a tumor and can spread to other parts of the body.

Lung cancer is often diagnosed once it has spread outside the lungs. About 9 out of every 10 people with lung cancer die from the disease because it is found after it has spread.

Who should be screened for lung cancer?

The United States Preventive Services Task Force (USPSTF) is made up of experts in preventive medicine. Without pay, they review the current research to make recommendations about clinical preventive services such as screening, counseling, and preventive medications.

The USPSTF recommends lung cancer screening for individuals who:

- Are 55 to 80 years old
- Do not have any signs or symptoms of lung cancer (diagnostic testing may be recommended for people who do have signs or symptoms of lung cancer)
- Have not had lung cancer before
- Currently smoke or quit less than 15 years ago
- Are or were heavy smokers (30 pack-years history such as those who smoked 1 pack per day for 30 years or 2 packs per day for 15 years)

The USPSTF does not recommend lung cancer screening for individuals who:

- Have a condition that greatly limits how long they may live
- Are not willing to have surgery for lung cancer

Possible signs and symptoms of lung cancer

- A new cough that does not go away or gets worse
- Chest pain that is often worse when you breathe deeply, cough, or laugh
- A hoarse voice
- Unexplained weight loss and loss of appetite
- Coughing up blood or rust-colored spit or phlegm
- Shortness of breath
- Infections such as bronchitis and pneumonia that do not go away or keep coming back
- Wheezing

Many patients with lung cancer do not have any symptoms when the cancer first starts. It is best to find lung cancer early before symptoms start, when the cancer is more easily treated. This is why screening is important.

If you have any signs or symptoms of lung cancer, be sure to tell your health care professional.

Calculating pack-years*

(20 cigarettes = 1 pack)

_____ Number of years smoked

× _____ Average number of packs smoked per day

= _____ Pack-years

* Your health care professional can help you determine the number of pack-years you have smoked.

Remember, the best way to lower your chances of dying from lung cancer is to stop smoking.

More than 8 out of every 10 lung cancer cases in the United States are from smoking.

Lung cancer screening should not be done instead of quitting 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).

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 with LDCT?*

BENEFIT: Greater chance of not dying from lung cancer

- If 1,000 people are not screened with LDCT for lung cancer, **21 will die from lung cancer.**
- If 1,000 people are screened with LDCT once a year 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)

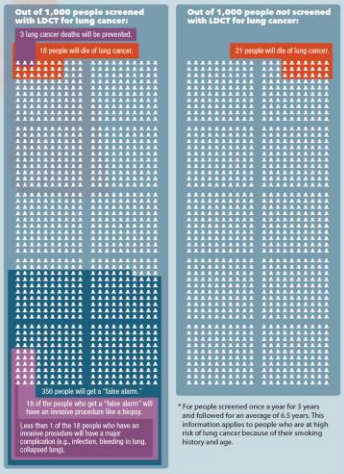
- If 1,000 people ar e not screened with LDCT for lung cancer, **75 will die from any cause.**
- If 1,000 people are screened with LDCT once a year for 3 years, **70 will die from any cause.**
- This means that with LDCT screening, **5 fewer people will die from all causes.**

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.



* 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 benefits of lung cancer screening may be greater if your lung cancer risk is higher. For example, current smokers who smoke more than one pack a day have a higher risk for lung cancer than smokers who quit 10 years ago.

The harms of lung cancer screening may be greater if you have other health problems, such as heart disease or severe lung disease like asthma or chronic obstructive pulmonary disease (COPD). The risk of problems from biopsies may be higher in these people.

What is lung cancer screening with low-dose computed tomography?

During an LDCT scan, you lie on a table and an x-ray machine uses a low dose (amount) of radiation to make detailed images of your lungs. The scan only takes a few minutes and is not painful.

HARM: Overdiagnosis

Lung cancer screening may find a lung cancer that would not have ever caused symptoms or harmed the patient in his or her lifetime if the cancer had not been found. This could lead to treatment of people who do not really need treatment.

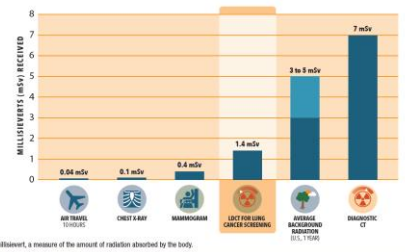
At the time of diagnosis, there is no way for health care professionals to know if the lung cancer will cause health problems over a lifetime. For this reason, almost all people who are diagnosed with lung cancer are treated.

Researchers found that out of every 10 people diagnosed with lung cancer after an LDCT scan, about 1 to 2 of those people are treated for cancer that likely never would have harmed them.

HARM: Radiation exposure

Exposure to radiation increases a person's chance of developing cancer. LDCT screening for lung cancer exposes a person to radiation. If the screening test is positive, additional testing may involve higher doses of radiation. Researchers do not know how being exposed to radiation from LDCT scans and additional diagnostic imaging tests may affect people. The figure below shows the amount of radiation from one LDCT scan compared with other sources of radiation.

COMPARING SOURCES OF RADIATION



mSv=millisievert, a measure of the amount of radiation absorbed by the body.

Finding other things that are not lung cancer

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 is the difference between screening and diagnostic testing?

Screening is a medical term for testing to find a disease *before it causes any symptoms or problems.* Lung cancer screening is done to find lung cancer before it has spread.

Diagnostic testing is not the same as screening. Diagnostic testing is done when someone has signs or symptoms of lung cancer or when a screening test finds something that looks like cancer. In both cases, there is a higher chance the person has lung cancer, and additional testing is done to get a final diagnosis. It is different from screening because it can involve scans with higher amounts of radiation, other tests to look at the lungs, and taking samples of lung tissue.

WHAT IS IMPORTANT TO YOU WHEN DECIDING ABOUT SCREENING FOR LUNG CANCER?

There are many things to think about when deciding whether lung cancer screening is right for you. Below is a list of questions that may help you decide.

	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?	○	○	○	○	○

TALKING WITH YOUR HEALTH CARE PROFESSIONAL ABOUT LUNG CANCER SCREENING

Making the decision to be screened for lung cancer is a personal decision. You should talk with your health care professional and make the decision based on what is right for you.

Below are some questions to think about at your visit with your health care professional. Keep in mind the possible benefits and harms that are most important to you.

- ○ Am I eligible for lung cancer screening?
- ○ What happens if I decide not to be screened for lung cancer?
- ○ Does my insurance cover lung cancer screening?
- ○ Where should I go for lung cancer screening?
- ○ Do I have to do anything to prepare for screening?
- ○ How soon will I know the results of screening?
- ○ What happens if the lung cancer screening shows something of concern?

WHAT ABOUT INSURANCE COVERAGE FOR LUNG CANCER SCREENING?

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

Medicare pays for lung cancer screening with no out-of-pocket costs for people up to age 77 if you meet the following criteria:

- You must have a written order from your health care professional (your doctor, nurse practitioner, or physician assistant).
- Your visit with your health care professional must be a "shared decisionmaking visit." In this visit your health care professional must use one or more decision aids and must discuss benefits and harms. Your health care professional must also talk about followup diagnostic testing, overdiagnosis, false alarms, and total radiation exposure from screening.
- You must go to a screening facility that participates in the lung cancer screening registry set up for Medicare patients.

Ask your health care professional about the criteria if you have Medicare coverage.

There may be additional costs for followup tests and/or treatments after the initial screening exam. Contact your insurance company to see if the procedures are covered and what the cost to you would be.

WHAT OTHER QUESTIONS DO YOU HAVE?

INFORMATION FOR CONSUMERS

- **Understanding Lung Cancer**
  www.cancer.gov/types/lung
- **Screening for Lung Cancer: Consumer Guide**
  www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/lung-cancer-screening
- **Find an Approved Screening Facility**
  www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilityIte/Lung-Cancer-Screening-Registries.html

WHAT IS YOUR DECISION ABOUT LUNG CANCER SCREENING?

- ○ Screening is right for me.
- ○ Screening is not right for me.
- ○ I am unsure about screening.

AHRQ Publication No. 16-EHC007-12-A
March 2016

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.**

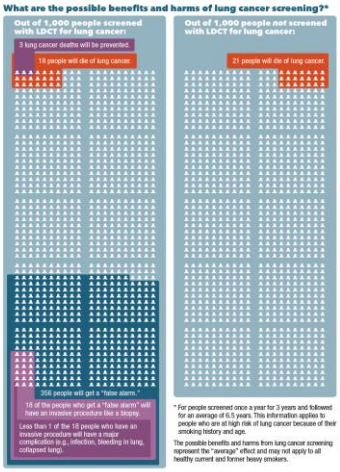
HARM: False alarms and unneeded additional testing

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.

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.

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

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?

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).

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.

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

AMERICAN LUNG ASSOCIATION. | LUNG FORCE

Is lung cancer screening right for me?

Screening is a test used to detect lung cancer before any symptoms appear. Screening with low-dose CT (LDCT) scans can reduce deaths in those at high risk. The test is not recommended for everyone and it has risks as well as benefits. Below are key points you may want to use in discussion with your doctor if you are worried about your risk for lung cancer.

Q: Am I a candidate for lung cancer screening?

A: If you meet the following criteria, you are considered to be at "high risk" for developing lung cancer and screening is recommended:

- 55-80 years of age
- Have a 30 pack-year history of smoking (this means 1 pack a day for 30 years, 2 packs a day for 15 years, etc.)
- AND, are a current smoker, or have quit within the last 15 years

At this time, there is not enough evidence to show that screening is recommended for other groups.

A note on insurance coverage:

If you are 55-80 years old and have private insurance or 55-77 years old and have Medicare, and meet the other high-risk criteria listed, the initial scan will be covered without cost-sharing.

Be sure to check with your insurance plan for screening coverage and for any additional procedures—there may be other costs associated even if the actual screening is free. Visit the Lung Cancer Screening Insurance Checklist for questions to ask your insurance provider.

Q: Why is lung cancer screening only recommended for a certain group of people?

A: Experts look at the available data and use complex equations to determine who should be screened. If you are not in the high-risk group that means data has shown the benefits of screening do not outweigh your risks. However, there are still important ways you can reduce your lung cancer risk, such as eliminating your exposure to tobacco smoke, radon in your home and other hazardous chemicals.

Join the American Lung Association's fight to increase federal funding for cancer research at the National Institutes of Health so there can be improved early detection for lung cancer, as well as better treatments and cures for all. Sign up today at LungAction.org.

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Q: How can I reduce my lung cancer risk if I am not a candidate for screening?

A: The best way to reduce your risk is to take steps to avoid exposure to the dangerous substances most likely to cause lung cancer.

- The best way is to never smoke or stop smoking now. If you smoke, talk to your doctor or contact the Lung HelpLine (1-800-LUNGUSA) about ways to help you quit. Visit Lung.org/stop-smoking for more information.
- Avoid exposure to secondhand smoke.
- Test your home for radon, an odorless gas that causes lung cancer. Radon can be found in any home. If your home tests high for radon, take steps to repair your home to remove the radon. A certified radon contractor can fix the problem. Learn more at Lung.org/radon.
- Make sure you are safe around hazardous materials in the workplace and at home.

Q: Should I get an LDCT scan to screen for lung cancer?

A: If you are at high risk, talk with your doctor about getting an LDCT scan to screen for lung cancer. Screening for lung cancer may save your life. Discuss your complete health history and ask for a clear explanation about the possible benefits and risk. There are some risks and not everyone should be screened for lung cancer. Only low-dose CT scans are recommended for screening. Chest x-rays are not recommended for lung cancer screening.

Q: What happens if I choose to get an LDCT scan for lung cancer?

A: There is some radiation risk with an LDCT scan and you may need to have additional tests and procedures. You should go to a hospital or screening center that has a team of experts who will clearly explain the procedure to you. The team should tell you about all the risks and benefits of the screening. They should also discuss what the results can mean and how they will follow up with you after the initial screening.

Q: What do the results mean?

A: A "positive" result means that the low-dose CT scan shows something abnormal. This is usually a nodule of a concerning size. You may need to have additional scans or other procedures to find out exactly what it is. These next steps should be discussed with you by your physician and/or the team of experts at the screening center.

A "negative" result means there were no abnormal findings at this time on this scan. Your doctor should discuss when and if you should be tested again.

1-800-LUNGUSA | Lung.org

AMERICAN LUNG ASSOCIATION. | LUNG FORCE

There may also be an "indeterminate" result and your doctor may recommend watchful follow-up and further imaging at a later time.

The best way to reduce your lung cancer risk is to never smoke or stop smoking. If you smoke, talk to your doctor about ways to help you quit.

Q: Where can I get more information about lung cancer and lung cancer screening?

A: The American Lung Association has a variety of lung cancer screening resources for patients and healthcare professionals. Visit SavedByTheScan.org or call the Lung Cancer HelpLine at 1-844-ALA-LUNG for more information.

1-800-LUNGUSA | Lung.org

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Questions to Ask Your Insurance Company about Coverage for Lung Cancer Screening

Lung cancer screening means testing for lung cancer before a person has any symptoms. Right now, many insurance companies are covering this service for those considered to be at high risk. However, before you decide to get a lung cancer screening, it is important to know exactly what your insurance will cover. Use the questions below as a guide for your conversations with your insurance company.

How Do I Contact My Insurance Company?
On the back of your insurance card, there will be a phone number for you to call. You will likely be asked for your plan information and group ID.

Notes: _____
_____

Questions to Ask when Planning for Screening

- ☐ Has my insurance company put together a website or a flyer on lung cancer screening coverage issues?
- ☐ Do I need to go to my primary care provider/my doctor before I get screened to get a referral or determine if screening is appropriate for me?
- ☐ What paperwork do I need to complete before, during or after that visit to ensure my screening is covered by insurance?

Notes: _____
_____

Questions to Ask about Scheduling the Screening

- ☐ Do I need a referral or preauthorization?
  a. If so, from whom?
  b. Who must this referral or preauthorization be sent to?
  c. Will my physician submit it or must I?
- ☐ Is there a certain place (facility or center) I need to go to for my screening?
  a. If the nearest facility is too far away from where I live, what do I do?
- ☐ Will my insurance cover my travel expenses to the screening?

Notes: _____
_____

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Questions to Ask Insurance Company about Costs

- ☐ Are all the costs of the screening completely covered or will I be charged any out of pocket expenses?
  a. Will I need to pay a facility fee?
  b. Are there other out of pocket costs I will need to pay?

Notes: _____

_____

Questions to Ask about Activities after the Screening

- ☐ Who do I follow-up with after my screening?
- ☐ Is my follow-up doctor's visit covered under my insurance?
  a. If not, what are the expected out of pocket expenses?
- ☐ What follow-up tests will I need if something is detected during screening and will my insurance cover those tests?
- ☐ If my doctor recommends screening every year, will it be covered by my insurance?
- ☐ Will my insurance cover counseling and medications that can help me quit smoking? What are my out of pocket expenses?

Notes: _____

_____

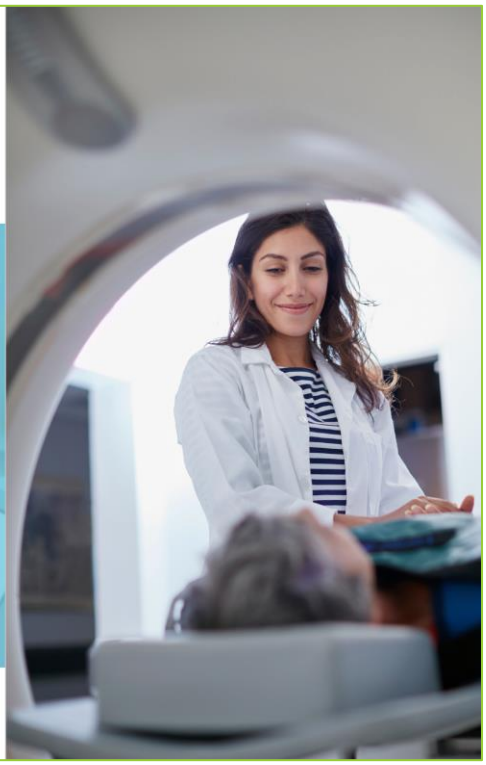
SavedByTheScan.org

GO2 FOUNDATION FOR LUNG CANCER

Empower Everyone. Ignore No One.

Understanding Lung Cancer Screening

1-800-298-2436 | go2foundation.org



What is Cancer Screening?

Cancer screening is a test to check for disease in someone who does not have any symptoms. Some examples of cancer screening include mammograms for breast cancer, pap smears for cervical cancer and colonoscopies for colorectal cancer. The goal of screening is to find cancer early when it is more treatable and even curable.

For lung cancer, low dose CT (LDCT) scans are the only proven method. Chest x-rays are not recommended for screening. To learn more see the patient education video on the "about screening" pages on our website at www.go2foundation.org.

Why Should I Consider Screening?

Studies have shown that screening those at high risk with LDCT scans before symptoms are present can find lung cancer early when it is easier to treat and more likely to be cured. Lung cancer screening might also show if you have other conditions or diseases that need to be treated.

Who Should Be Screened for Lung Cancer?

Annual screening is recommended for individuals whose age and smoking history place them at higher risk for lung cancer. This means they have at least a 30 pack year* smoking history and currently smoke or quit within 15 years. Most commercial insurances cover individuals aged 55–80, while Medicare covers those aged 55–77.

There is some research to support screening people who may be younger or who have smoked less but who also have another factor that increases their risk of lung cancer, such as a diagnosis of COPD, a family history of lung cancer or job exposure to cancer-causing agents like radon and asbestos. Tell your doctor and find out if a low-dose CT scan is right for you. Note that screening for other risk factors may have a co-pay and deductible applied.

***How to calculate your pack years:** Average number of packs smoked per day X number of years as a smoker = your pack years (Example 1: 1 pack a day for 30 years = 30 pack years, Example 2: 2 packs a day for 15 years = 30 pack years)

What Happens During a Low Dose CT Screening Test?

A machine called a CT scanner takes 3D x-ray pictures of your lungs using a small amount of radiation (also called a low dose CT). This level of radiation is more than a chest x-ray but is much lower than other types of CT scans.

This screening test for lung cancer is quick and painless. It requires no needles or dye. Typically, your clothing can be left in place, and there is no need to limit eating or drinking prior to the test. Lung cancer screening takes about 10 minutes, and the actual scan only takes a few seconds.

Currently, this screening test is the only one that can find lung cancer early, which allows more treatment options to save lives.

Are There Risks Involved With Screening?

As with all cancer screening tests, this test is not perfect. Some cancers may still be missed. Some scans may show spots in the lung that look suspicious but may not be cancerous. These are called false positives. Similar to moles on the skin, your lungs may have nodules or spots that are watched but are normal or non-cancerous.

When needed, your doctor may recommend additional testing to diagnose or rule out lung cancer. Usually that is another low-dose CT in a few months to see if the spots found during your screening have changed. Every low-dose CT scan—whether your screening test or a follow-up scan—involves a small amount of radiation. In some instances, your doctor may refer you for minimally invasive tissue sampling/biopsy, or possible surgery or other treatments.

How Often Should I Be Screened?

Lung cancer can be aggressive and advance quickly between stages. This is why it is important to be tested every year until you are out of the recommended age range or for as long as your doctor recommends. Regular screenings will let your doctor see if spots in your lungs are stable or whether any changes over time may be more suspicious for cancer. Screening for lung cancer before symptoms appear is important. Without it, most people do not see signs of the disease until it has spread to other areas of the body, making it harder to treat. Talk to your doctor about the results of your screening to determine what you need to do next.

Is Screening Covered by Insurance?

For individuals who meet the high-risk criteria, low dose CT screening for lung cancer is covered every year by Medicare and most private insurance plans at 100% with no out-of-pocket cost—just like mammograms and other screening tests. However, additional testing and follow-up scans between screenings may have a cost, such as a co-pay or deductible. Ask your doctor if your insurance covers the test.

Where Should I Be Screened?

You should be screened for lung cancer in an experienced center that follows approved guidelines for lung cancer screening. For example, there are GO_2 Foundation-designated Screening Centers of Excellence nationwide. To find a center near you, call our HelpLine at 1-800-298-2436 or visit our website at www.go2foundation.org.

Lung cancer screening with a low dose CT scan is recommended by leading advocacy, government and medical groups, including GO_2 Foundation for Lung Cancer, Federal Government Agencies (Centers for Medicare & Medicaid Services), the United States Preventive Services Task Force (USPSTF), the National Comprehensive Cancer Network (NCCN), American College of Radiology, and the American Cancer Society.

Choosing a Screening Program

If you do not live near a GO_2 Foundation-designated Screening Center of Excellence, here are some questions to ask your local screening center to determine if they are screening responsibly:

1. What test do you use to screen for lung cancer?
The test should be a LDCT scan, which means that the radiation amount is much lower than in a regular CT scan.

2. Who will interpret the scan?
LDCT scans can be more challenging to read than regular CT scans. It is best for a radiologist with experience reading and reporting LDCT scans of the chest to be the one to interpret your scan.

3. What guidelines will be used if something is found?
Several professional organizations have developed clinical guidelines specifically for lung cancer screening and your center should consistently follow one of them.

4. What will happen if something is found?
Your screening program should work with your primary care provider to arrange any follow-up tests or care that you need, preferably from a team of doctors who will work together to evaluate and treat you.

5. Who is eligible for screening in your program?
Annual screening is recommended for individuals whose age and smoking history place them at higher risk for lung cancer. This means they have at least a 30 pack year* smoking history and currently smoke or quit within 15 years. Most commercial insurances cover individuals aged 55–80, while Medicare covers those aged 55–77.

There is some research to support screening people who may be younger or who have smoked less but who also have another health condition that increases their risk of lung cancer, such as a diagnosis of COPD, a family history of lung cancer or job exposure to cancer-causing agents like radon and asbestos. Tell your doctor and find out if a low-dose CT scan is right for you. Note that screening for other risk factors may have a co-pay and deductible applied.

Contact us if you have questions
1-800-298-2436 | info@go2foundation.org
go2foundation.org

WHERE CAN I GO FOR MORE INFORMATION?

For more information about lung cancer, treatments and clinical trials, to discuss support options or for referral to other resources, please contact us.

HELPLINE | 1-800-298-2436 or support@go2foundation.org

SCREENING CENTERS OF EXCELLENCE
under Risk & Early Detection at go2foundation.org

WEBSITE | go2foundation.org

GO2 FOUNDATION FOR LUNG CANCER
Empower Everyone. Ignore No One.

GO2 FOUNDATION FOR LUNG CANCER

1700 K Street, NW, Suite 660, Washington, DC 20006
1100 Industrial Road, #1, San Carlos, CA 94070

Founded by patients and survivors, GO_2 Foundation for Lung Cancer transforms survivorship as the world's leading organization dedicated to saving, extending, and improving the lives of those vulnerable, at risk, and diagnosed with lung cancer.

GO_2 Foundation works to change the reality of living with lung cancer by ending stigma, increasing public and private research funding, and ensuring access to care.

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APPENDIX J. QUESTIONNAIRE PERMISSION

Hi Teresa,

Thanks for your email. You have our permission to use any questionnaire items in our survey. The questionnaire was adapted from the NCI questionnaires as cited in our papers.

The specific items related to guideline eligibility, however, are original since these guidelines did not previously exist. We created them originally at Wake Forest in 2012-2013 based on all of the guidelines available at the time with a group of cancer screening and health services researchers (see paper: DOI 10.1158/1055-9965.EPI-14-1241). These items were pilot tested with cognitive interviews prior to use.

We re-used these items but adapted for the USPSTF recommendations and CMS coverage criteria for the 2017 survey published in JNCCN. We also pilot tested these items again with physicians at both Vanderbilt and the VA prior to use and performed cognitive interviews. There has not been any formal psychometric testing on these items.

Let us know if you have any other questions.

Thanks,

Jennifer

Jennifer Lewis, MD, MS, MPH
VA Quality Scholars Fellow, VA TVHS
Co-Director, VA TVHS Lung Cancer Screening Program
Instructor, Division of Hematology/Oncology
Vanderbilt University Medical Center

APPENDIX K. SURVEY QUESTIONS

This survey includes items related to share decision-making, lung cancer screening, and demographic questions.

The below items 1 – 3 relate to shared decision-making.

1. How confident are you in initiating a shared decision-making discussion with a patient considering lung cancer screening?
    a. Not confident at all
    b. Somewhat confident
    c. Very confident

2. Which of the following elements are required for CMS reimbursement for shared decision-making in lung cancer screening *(Select all that apply)?*
    a. Benefits of screening
    b. Harms of screening
    c. False positives
    d. Follow-up testing
    e. Overdiagnosis
    f. Total radiation exposure
    g. Importance of adherence to annual screening
    h. Impact of comorbidities
    i. Ability or willing ness to undergo diagnosis and treatment
    j. Importance of maintaining cigarette smoking abstinence if former smoker
    k. Importance of smoking cessation if current smoker Information about tobacco cessation interventions
    l. Other (please specify):
    m. Don’t know

3. Which of the following statements need to be included in the shared decision-making documentation for CMS reimbursement for patients considering lung cancer screening *(Select all the apply)?*
    a. Patient date of birth or age
    b. Specific pack-years smoking history
    c. Current smoking status
    d. Number of years since quitting smoking for former smokers
    e. Statement that the patient does not have any signs or symptoms of lung cancer
    f. Statement that the patient does not have a family history of lung cancer
    g. Other (please specify)
    h. Don’t know

The below items 4 – 9 relate to lung cancer screening guidelines:

4. At what age are patients eligible to begin lung cancer screening with low dose CT?
    a. 30
    b. 35
    c. 40
    d. 45
    e. 50
    f. 55
    g. 60
    h. 65
    i. Other (please specify)
    j. Don't know
5. At what age are patients no longer eligible for lung cancer screening with low dose CT?
    a. 65
    b. 70
    c. 75
    d. 76
    e. 77
    f. 78
    g. 79
    h. 80
    i. 81
    j. 85
    k. Other (other please specify)
    l. No Upper age limits
    m. Don't know
6. To qualify for lung cancer screening with LDCT, what is the minimum number of cigarette pack years (packs/day x years smoked) that a patient must have?
    a. 10 pack years
    b. 20 pack years
    c. 30 pack years
    d. 40 pack years
    e. 50 pack years
    f. Other (please specify):
    g. Don't know
7. If a patient meets the minimum cigarette pack year requirement for LDCT screening, is it recommended for:
    a. Current smokers only
    b. Former smokers only
    c. Both current and former smokers
    d. Don't know
8. Is LDCT recommended for patient with multiple, chronic comorbidities who are unable to undergo surgery?
    a. Yes
    b. No
    c. Don't know
9. What is the recommended frequency for LDCT screening? Is it every:
    a. 1 year
    b. 2 years
    c. 4 years
    d. 5 years
    e. 10 years
    f. Other (please specify)
    g. Don't know

The below items 10 – 11 are demographic questions about your practice:

10. What is your profession?
    a. Physician
    b. Physician Assistant
    c. Nurse Practitioner
    d. Clinic Support staff (Nurse, MA, Other Clinic Staff)

11. How many years have you been in clinical practice?
    a. 0-3 years
    b. 4-6 years
    c. 7-9 years
    d. 10-12 years
    e. Greater than 12 years

APPENDIX L. EDUCATION SESSION EVALUATION

Please complete the following education session evaluation questions.

1. The objectives in the lung cancer educational presentation were met
    a. Strongly agree
    b. Somewhat agree
    c. Neutral
    d. Somewhat disagree
    e. Strongly disagree

2. The content in the lung cancer educational presentation met my educational needs.
    a. Strongly agree
    b. Somewhat agree
    c. Neutral
    d. Somewhat disagree
    e. Strongly disagree

3. The content in the lung cancer educational presentation will be beneficial to my practice.
    a. Strongly agree
    b. Somewhat agree
    c. Neutral
    d. Somewhat disagree
    e. Strongly disagree

4. The content was easy to understand and free of bias.
    a. Strongly agree
    b. Somewhat agree
    c. Neutral
    d. Somewhat disagree
    e. Strongly disagree

5. Any other comments:

6. Is there anything else related to lung cancer screening and shared decision-making you would have wanted to be included in the education in-service?

Comments:

APPENDIX M. TOOLKIT EVALUATION

Please complete the following lung cancer screening toolkit evaluation questions.

1. The content in the lung cancer screening toolkit met my educational needs.
    a. Strongly agree
    b. Somewhat agree
    c. Neutral
    d. Somewhat disagree
    e. Strongly disagree

2. The content in the lung cancer screening toolkit will be beneficial to my practice.
    a. Strongly agree
    b. Somewhat agree
    c. Neutral
    d. Somewhat disagree
    e. Strongly disagree

3. The content in the lung cancer screening toolkit was easy to understand and free of bias.
    a. Strongly agree
    b. Somewhat agree
    c. Neutral
    d. Somewhat disagree
    e. Strongly disagree

4. Any other comments:

5. Is there anything else related to lung cancer screening and shared decision-making you would have wanted to be included in the lung cancer screening toolkit?

Comments:

APPENDIX N. DATA COLLECTION FORM

			Past smoker		Amt Smoked				SDM Eligibility			SDM Required Elements							SDM Counseling Requirements			
No.	Age	Smoker	Quit Date	≤ 15 Years	Pack Years	≥ 30 Years	LCS Eligible	SDM	S/S	HX	Quit	DA	B	H	FU	OD	FP	RE	Annual Screen	Co-Morbid	Able Will	Smoke Cessation