2017

An Educational Toolkit to Promote Lung Cancer Screening in Primary Care

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Date of Submission:	April 21, 2017

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Abstract

Lung cancer is the leading cause of cancer mortality in the United States for both men and women. Lung cancer screening with low-dose computed tomography (LDCT) demonstrates reductions in lung cancer mortality and all-cause mortality, and improved rates of early stage diagnosis in high-risk current and former adult smokers. Evidence-based screening guidelines include annual LDCT in high-risk current and former adult smokers; however, these guidelines have not been fully translated into clinical practice. The purpose of this project was to create a toolkit for lung cancer screening to assist primary care providers in educating and screening their patients at high-risk for lung cancer with an overall goal of reducing lung cancer mortality and improving early stage diagnosis of lung cancer. An educational intervention using single group post-test was carried out in a primary care practice. Providers were asked to use a toolkit that included resources for lung cancer screening in clinical practice. Survey data was collected to determine effectiveness of the toolkit and educational intervention. Analysis of the data indicated that the toolkit may be beneficial to practice, although there were provider concerns about time and patient receptiveness. Lung cancer is a significant cause of mortality; giving providers tools to educate and screen high-risk patients for lung cancer may reduce mortality rates and improve survival.

Keywords: computed tomography, decision aid, education, high-risk adult smokers, low-dose computed tomography, lung cancer, lung cancer screening, patient, primary care, toolkit

An Educational Toolkit to Promote Lung Cancer Screening in Primary Care

Introduction

Lung cancer is the number one cause of cancer death in the United States despite a steady reduction in lung cancer mortality rates since 1990 (American Cancer Society [ACS], 2016a; Boiselle, 2013; Manser et al., 2013; Moyer, 2014). When diagnosed at stage I, five-year survival rates range from 45% to 49% (ACS, 2016a). Seventy-nine percent of lung cancers are diagnosed when cancer has already metastasized to lymph nodes or distant areas, and survival rates are significantly reduced (ACS, 2016a; Bach et al., 2012; Surveillance, Epidemiology, and End Results Program [SEER], 2016; Wender et al., 2013). In 2010, the National Lung Screening Trial Research Team (2011) released results from their large randomized controlled trial (RCT) showing a significant reduction in lung cancer mortality rates with annual low-dose computed tomography (LDCT) in high-risk current and former adult smokers. Based on these results, the ACS and the United States Preventive Service Task Force (USPSTF) released guidelines in 2013 recommending annual LDCT for lung cancer screening in adults with a significant history of smoking. The purpose of this Doctor of Nursing Practice (DNP) project was to create a toolkit for lung cancer screening to assist primary care providers in educating and screening their patients at high-risk for lung cancer, with an overall goal of reducing lung cancer mortality and improving rates of early stage diagnosis of lung cancer.

Evidence of the Problem

In both men and women, lung cancer is the leading cause of cancer death, accounting for approximately 25% of cancer mortality (ACS, 2016a). In 2013 in the United States, 212,584 individuals were diagnosed with lung cancer while 156,176 individuals died from lung cancer (Division of Cancer Prevention and Control, 2016). Estimates for 2017 predict 222,500 new

cases of lung cancer and 155,870 deaths from lung cancer (ACS, 2017). As the statistics demonstrate, lung cancer is prevalent in the United States and is a significant cause of mortality. Even when diagnosed early at stage I, non-small cell lung cancer (NSCLC) has a five-year survival rate of 45% to 49%, whereas stage I small cell lung cancer (SCLC) has a five-year survival rate of 31% (ACS, 2016a; ACS, 2016b). About 57% of lung and bronchus cancers are diagnosed after metastasis to distant areas, and the five-year relative survival rate is only 4.2% at that stage (SEER, 2016). About 16% of lung and bronchus cancers are diagnosed at a local site, indicating that only 16% will have favorable survival rates (SEER, 2016).

Smoking is the leading cause of lung cancer and accounts for 80% of deaths from lung cancer (ACS, 2016a). Individuals who currently smoke and those who have quit are both at risk as lung cancer develops over approximately 20 years (Manser et al., 2013). As compared to non-smokers, individuals who smoke are 15 to 30 times more at risk of developing lung cancer and dying from lung cancer (Centers for Disease Control and Prevention, 2015). Efforts have been made toward smoking cessation in various ways such as banning smoking in certain areas, discussing smoking cessation with patients, informing the public of its adverse effects, making it a national objective, and retail stores not selling tobacco products (Office of Disease Prevention and Health Promotion, 2017). In addition to a history of smoking, the elderly are more likely to develop lung cancer; about two of three individuals diagnosed with lung cancer are 65 years of age or older, while less than two percent are younger than 45 years of age (ACS, 2016a). The chance of a male developing lung cancer in his lifetime is one in 14, while this chance is one in 17 for women (ACS, 2016a).

Beginning in the 1970s and 1980s, studies were conducted to determine if screening with chest x-ray (CXR) with or without sputum cytology would reduce lung cancer mortality (Wender

et al., 2013). Four RCTs were conducted with this design and failed to show a statistically significant reduction in lung cancer mortality (Wender et al., 2013). Subsequently, the ACS removed its recommendation for lung cancer screening with CXR for current and former smokers (Wender et al., 2013). Further efforts to determine an effective screening method to diagnose lung cancer at an earlier stage for high-risk individuals continued (Wender et al, 2013). In observational studies, LDCT of the chest was able to identify more lung cancers and nodules than chest radiography (The National Lung Screening Trial Research Team, 2011). Non-comparative cohort studies with an evaluation of LDCT for lung cancer screening have also been conducted.

RCTs that compared LDCT to CXR with or without sputum cytology and no screening have been conducted. The largest of these trials was the National Lung Screening Trial (NLST), where researchers randomly assigned 53,454 current and former adult smokers at high-risk of developing lung cancer to receive annual LDCT or CXR (The National Lung Screening Trial Research Team, 2011). In this study, there were 247 deaths from lung cancer per 100,000 person-years in the LDCT group versus 309 deaths per 100,000 person-years in the CXR group, resulting in a relative reduction in lung cancer mortality of 20% with LDCT screening (95% CI, 6.8-26.7; $p = .004$); screening with LDCT detected more stage I lung cancers than CXR in this study (50% vs. 31.1%, respectively) (The National Lung Screening Trial Research Team, 2011). Over the past few years, several organizations, including the ACS and the USPSTF, have released guidelines for lung cancer screening that recommend LDCT in a high-risk population of current and former adult smokers. These guidelines are based primarily on the findings of the NLST, but findings from other RCTs and cohorts were included in the reviews. Organizational guidelines differ in the criteria utilized to determine which individuals are eligible to be

screened. The American Academy of Family Physicians (AAFP) (2013) does not even support LDCT for lung cancer screening; the AAFP believes that the evidence is insufficient to recommend for or against screening.

Several systematic reviews regarding lung cancer screening with LDCT have been published (Acikgoz et al., 2014; Bach, Kelley, Tate, & McCrory, 2003; Bach et al., 2012; Bach, Silvestri, Hanger, & Jett, 2007; Black et al., 2006; Boiselle, 2013; Humphrey et al., 2013; Humphrey, Teutsch, & Johnson, 2004; Manser et al., 2013; Midthun & Jett, 2008; Ravenel, Costello, & Silvestri, 2008; Slatore, Sullivan, Pappas, & Humphrey, 2014). The effectiveness of LDCT and its risks versus benefits were evaluated in these reviews. Although a significant reduction in lung cancer mortality was demonstrated in the NLST, other studies did not have similar significant findings. There are also harms with LDCT as a screening technique for lung cancer including false-positives, incidental findings, invasive procedures, over-diagnosis, and radiation exposure (Wender et al., 2013). False-positives can lead to additional testing, emotional distress, and invasive procedures that may result in a benign finding. The authors of these reviews have concluded that more data is needed to weigh benefits versus risks and determine cost-effectiveness of LDCT for lung cancer screening. As LDCT is recommended in high-risk individuals, providers should have a discussion regarding risks versus benefits with their patients who are high-risk for developing lung cancer. Lung cancer screening is also the first cancer screening modality that requires documentation of a shared decision-making visit for reimbursement by the Centers for Medicare and Medicaid Services (CMS) (Carter-Harris, Tan, Salloum, & Young-Wolff, 2016).

Problem Statement

Current and former smokers are at an increased risk of developing lung cancer. This is a

significant health problem as prognosis is poor when lung cancer is diagnosed at a late stage. LDCT has become a promising screening tool for lung cancer in individuals with a significant history of smoking. Although lung cancer screening guidelines by the ACS and USPSTF were released in 2013, it takes time for primary care providers to implement routine screening into daily practice. Mortality from lung cancer among high-risk current and former adult smokers is indicated by high lung cancer mortality rates, late stage diagnosis of lung cancer, and lack of adherence to lung cancer screening guidelines in primary care. To address the identified problem, a toolkit was created to assist primary care providers in educating and screening their patients at high-risk for lung cancer, with an overall goal of reducing lung cancer mortality and improving rates of early stage diagnosis of lung cancer.

Review of the Literature

The poor survival rates of lung cancer and the positive findings of LDCT for lung cancer screening in the NLST warrants an additional review of the literature to determine benefits versus harms. The literature was searched for publications that included a discussion of the effectiveness of LDCT for lung cancer screening. Cumulative Index of Nursing and Allied Health Literature (CINAHL) and Academic Search Premier were searched with the following keywords: “computed tomography”, “lung cancer”, and “screening”. An additional limiter was research studies only when searching CINAHL. Studies published in the English language and full text articles that were available through University of Massachusetts Amherst links were considered for inclusion in this review; these links allowed access to articles from databases such as Cochrane Library, Ovid, PubMed Central, and Science Direct. Studies published from January 01, 2000 to June 11, 2016 were considered for inclusion.

Studies that evaluated LDCT for lung cancer screening were considered for inclusion in

this integrative review. Comparators included CXR, sputum cytology, positron emission tomography, and no screening. There were no limitations on the type of setting that the studies were conducted in. RCTs were preferred, but cohort designs were considered if LDCT for lung cancer screening was the intervention of choice. This review considered studies with the following outcomes: lung cancer mortality, all-cause mortality, and stage at diagnosis of lung cancer. The highest levels of evidence were sought, and studies were rated using the John Hopkins Nursing Evidence-Based Practice (JHNEBP) Model (Dearholt & Dang, 2012).

Selected studies were limited to those whose samples included males and females aged 50 years and older who were current or former smokers with at least a 10 pack-year history of smoking. Large studies with sample sizes of 500 participants and above were included. It was preferred that participants of the studies reviewed had no history of lung cancer or other cancer, but studies that included participants with a history of cancer were considered for inclusion.

Results and Discussion

The search yielded 836 articles, which were scanned for inclusion in this integrative review. Of those articles, 42 were thoroughly evaluated to determine if they met inclusion criteria. Nine studies were excluded due to age of participants, seven due to presence of nonsmokers in the study population, seven due to outcomes, six due to duplication of studies, three due to sample size, and one due to inability to access the full article. Of the 15 included studies, seven were RCTs, and eight were cohort studies. Of the RCTs, three compared LDCT to CXR, while four compared LDCT to no screening. The NLST was the largest of the trials, where 26,722 participants were randomized to the LDCT group and 26,732 participants to the CXR group (The National Lung Screening Trial Research Team, 2011). Gohagan et al. (2005) compared LDCT to CXR with 1,660 in the LDCT arm and 1,658 in the CXR arm, while

Blanchon et al. (2007) randomized 385 participants to the LDCT arm and 380 participants to the CXR arm. The NLST participants and the Depiscan study participants received a total of three scans, while participants in the Lung Screening Study received a total of two scans (Blanchon et al., 2007; Gohagan et al., 2005; The National Lung Screening Trial Research Team, 2011). In the remaining four RCTs, the control groups received an annual clinical review only. Sample sizes of these studies varied from 2,450 in the Detection and Screening of Early Lung Cancer with Novel Imaging Technology (DANTE) study to 4,104 in the Danish Lung Cancer Screening Trial (DLCST) (Infante et al., 2015; Saghir et al., 2012). Participants in the DANTE trial, the DLCST, and the German Lung Cancer Screening Intervention Trial (LUSI) received a total of five annual LDCT scans, while participants in the ITALUNG trial received a total of four scans (Becker et al., 2015; Infante et al., 2015; Pegna et al., 2013; Saghir et al., 2012).

The eight cohort studies had sample sizes that ranged from 1,000 to 7,915 (Horeweg et al., 2014; Roberts et al., 2007). The number of computed tomography (CT) scans performed varied. Participants in Greenberg et al.'s (2012) study and Veronesi et al.'s (2013) study received up to 10 CT scans. Participants in Veronesi et al.'s (2014) and Menezes et al.'s (2010) studies received up to five annual LDCT scans, while three scans were performed in the NELSON trial (Horeweg et al., 2014). A baseline scan and one annual scan were performed in Wilson et al.'s (2008) study. Roberts et al. (2007) performed one single scan for their participants. It is not clear how many scans each participant received in Dhopeshwarkar et al.'s (2011) study. Participants in the majority of the studies in this integrative review received screenings annually, but some participants received scans biennially in Greenberg et al.'s (2012) study. In the NELSON trial, Horeweg et al. (2014) performed scans with increasing screening intervals at one, two, and 2.5 years.

All participants in these studies were current or former smokers aged 50 years and older with at least a 10 pack-year history of smoking. Seven of the studies required that smokers had quit within the past 10 years (Gohagan et al., 2005; Horeweg et al., 2014; Infante et al., 2015; Saghir et al., 2012; Veronesi et al., 2013; Veronesi et al., 2014; Wilson et al., 2008). The National Lung Screening Trial Research Team (2011) and Blanchon et al. (2007) included participants who had quit smoking within the past 15 years, while the remaining studies included all former smokers (Becker et al., 2015; Dhopeshwarkar et al., 2011; Greenberg et al., 2012; Menezes et al., 2010; Pegna et al., 2013; Roberts et al., 2007). The studies in this review included healthy participants; some exclusion criteria included history of cancer (except non-melanoma skin cancer), presence of a condition limiting life expectancy, recent chest CT scan, or participation in another lung screening study.

Lung cancer mortality. Results on lung cancer mortality were reported in three RCTs and two cohort studies (Infante et al., 2015; Saghir et al., 2012; The National Lung Screening Trial Research Team, 2011; Veronesi et al., 2013; Veronesi et al., 2014). The National Lung Screening Trial Research Team (2011) reported a relative reduction in lung cancer mortality of 20% with LDCT (95% CI, 6.8-26.7; $p = .004$); the rate of death from lung cancer in the LDCT group was 247 per 100,000 person-years and 309 per 100,000 person-years in the CXR group. Infante et al. (2015) and Saghir et al. (2012) found no statistically significant differences in mortality between screening groups. In Saghir et al.'s (2012) study, there were 15 (0.73%) deaths from lung cancer in the LDCT group as compared to 11 (0.54%) in the control group ($p = .428$). Infante et al. (2015) found a lung cancer mortality rate of 543 per 100,000 person-years in the LDCT arm versus 544 per 100,000 person-years in the control arm (hazard ratio, 0.993; 95% CI, 0.688-1.433). Veronesi et al. (2014) reported that 28 of 136 deaths (20.59%) were due to

lung cancer. Over the 10-year period, 23 deaths (38%) due to lung cancer occurred in Veronesi et al.'s (2013) study.

All-cause mortality. In four RCTs and two cohort studies, results were reported on all-cause mortality (Becker et al., 2015; Infante et al., 2015; Saghir et al., 2012; The National Lung Screening Trial Research Team, 2011; Veronesi et al., 2013; Veronesi et al., 2014). The National Lung Screening Trial Research Team (2011) found a statistically significant difference between all-cause mortality rates in the two groups which produced an overall mortality reduction with LDCT of 6.7% (95% CI, 1.2-13.6, $p = .02$); there were 1,877 deaths in the LDCT group and 2,000 deaths in the CXR group. Notably, when excluding deaths from lung cancer in the comparison, the reduction in overall mortality with LDCT decreased to 3.2% and was no longer significant ($p = .28$) (The National Lung Screening Trial Research Team, 2011) . Becker et al. (2015), Infante et al. (2015), and Saghir et al. (2012) did not find statistically significant differences in all-cause mortality rates between groups. Veronesi et al. (2013) found 60 total deaths over a 10-year period, resulting in a mortality rate of 0.67 per 100 person-years; causes other than lung cancer included cardiovascular disease (17%), other cancer (20%), and other causes (25%). Veronesi et al. (2014) reported 136 deaths.

Findings on mortality rates were only statistically significant in the NLST (The National Lung Screening Trial Research Team, 2011). This is likely due to the large sample size in the NLST. There was not enough power in the other studies to produce a statistically significant difference in mortality rates between groups. But, there are other aspects of the studies to consider when comparing mortality rates. The National Lung Screening Trial Research Team (2011) performed three annual scans, while there were five total scans in the other studies (Becker et al., 2015; Infante et al., 2015; Saghir et al., 2012; Veronesi et al., 2014). Follow-up

times also varied between studies. For the RCTs, Saghir et al. (2012) had the shortest median follow-up of 4.81 years, while Infante et al. (2015) had the longest median follow-up of 8.35 years. The National Lung Screening Trial Research Team (2011) followed participants for a median of 6.5 years, while Becker et al. (2015) followed participants for a range of three to 6.5 years; follow-up is still being conducted in the LUSI trial. An additional difference between studies is the criteria for inclusion; the studies differed between years since smoking cessation, as outlined above.

Stage at diagnosis. All of the studies in this integrative review contained reports of results on stage of lung cancer at diagnosis. Of the RCTs, findings from three studies included statistically significant differences for stage at diagnosis of lung cancer between groups. In the NLST, 63% of lung cancers were stage I in the LDCT group after a positive screening result as compared to 47.6% in the CXR group (The National Lung Screening Trial Research Team, 2011). Saghir et al. (2012) found that 70% of lung cancers diagnosed in the LDCT group were early stage (I-IIB) (48 of 69) as compared to 33% in the control group (8 of 33). In the DANTE trial, there was a higher number of stage I lung cancers diagnosed in the LDCT group as compared to the control group (47 vs. 16, $p = .0002$) (Infante et al., 2015). Gohagan et al.'s (2005) results did not produce a statistically significant difference in stage at diagnosis between groups; in the LDCT arm, 48% of lung cancers were stage I as compared to 40% in the CXR arm. In the ITALUNG trial, 23 of 35 (66%) screen-detected lung cancers were stage I, while 42 of 58 (72%) screen-detected lung cancers were stage I in the LUSI trial (Becker et al., 2015; Pegna et al., 2013). Blanchon et al. (2007) found that three of eight (38%) LDCT-diagnosed lung cancers were stage I, while the only (100%) CXR-diagnosed lung cancer was stage I.

The majority of lung cancers diagnosed by LDCT in the cohort studies were stage I.

Veronesi et al. (2013) reported that 55 of 71 (78%) LDCT-diagnosed lung cancers were stage I. Forty of 69 (58%) NSCLC cases were stage I in the Pittsburgh Lung Screening Study, and 44 of 65 (68%) lung cancer cases were stage I in Menezes et al.'s (2010) study (Wilson et al., 2008). Of 81 NSCLCs diagnosed in Dhopeshwarkar et al.'s (2011) study, 55 were stage I (68%). One hundred thirty-six of 175 (78%) lung cancer cases were stage I in Veronesi et al.'s (2014) study. Roberts et al. (2007) diagnosed 20 lung cancers by LDCT in their 1,000 participants (2%); nineteen were NSCLC, while one was SCLC. Of the 19 NSCLC cases, 15 were stage I (78%) (Roberts et al., 2007). Of 33 lung cancers diagnosed by LDCT in Greenberg et al.'s (2012) study, 26 (79%) were stage I.

Per these results, screening with LDCT results in detection of more lung cancers at an earlier stage; this leads to better prognosis for individuals diagnosed with lung cancer. The National Lung Screening Trial Research Team (2011) found that screening with LDCT resulted in more diagnoses of lung cancer versus CXR, but Gohagan et al. (2005) did not produce these results. Due to the smaller sample size in Gohagan et al.'s (2005) study, only 60 lung cancers were detected between both groups as compared to 2,001 lung cancers being diagnosed in the NLST (The National Lung Screening Trial Research Team, 2011). Earlier stage diagnosis with LDCT screening in the majority of the studies in this integrative review demonstrates the usefulness of LDCT as a screening tool for lung cancer. Improved rates of earlier stage diagnosis of lung cancer can subsequently reduce lung cancer mortality rates. If screening for lung cancer with LDCT were implemented at a national level, about 18,000 lung cancer deaths could be prevented annually (Goulart & Ramsey, 2013). Although importantly, these benefits need to be weighed against the unintended harms and adverse effects of screening for persons exposed to LDCT who did not have lung cancer. This is possible if patients who meet USPSTF

eligibility criteria are routinely identified by their primary care providers, educated about lung cancer screening, referred for LDCT annually, and compliant with follow-up protocols.

Education and Shared Decision-Making

Although there are few studies that evaluate the effect of lung cancer screening with LDCT on lung cancer mortality and all-cause mortality, findings from the largest RCT, the NLST, were statistically significant; there was a 20% relative reduction in mortality from lung cancer when LDCT was used (The National Lung Screening Trial Research Team, 2011). Other studies that evaluated mortality did not have these significant findings, but these trials had much smaller sample sizes as compared to the NLST (Becker et al., 2015: Infante et al., 2015; Saghir et al., 2012; Veronesi et al., 2014). There were high rates of earlier stage diagnosis with LDCT in the majority of studies in this integrative review. Based on these promising findings and poor survival rates with late stage diagnosis of lung cancer, the recommendations of the USPSTF for lung cancer screening with LDCT should be implemented.

The USPSTF recommends annual lung cancer screening with LDCT in adults aged 55 to 80 years with at least a 30 pack-year history of smoking; this includes current smokers and former smokers who have quit within the past 15 years (Moyer, 2014). Screening should be discontinued when it has been 15 years since quit date, when the patient turns 81 years old, or when comorbidity is present that significantly reduces life expectancy or the ability to have lung surgery (Moyer, 2014). For patients who meet these criteria, the provider should have a discussion with the patient regarding risks and benefits of screening with LDCT and form a shared decision. The USPSTF's recommendation for lung cancer screening with LDCT is a Grade B recommendation, 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" (USPSTF, 2016).

The USPSTF also supports adherence to standardized follow-up protocols; the National Comprehensive Cancer Network (2014) has established protocols for follow-up on LDCT lung cancer screening (Moyer, 2014).

Screening for lung cancer is the first cancer screening modality that requires documentation of a shared decision-making visit for reimbursement by the CMS (Carter-Harris et al., 2016). Shared decision-making is a process that occurs between the patient and provider where the patient's values regarding medical decisions are considered, and the patient is the focus of care (Delbanco & Gerteis, 2015). The USPSTF recommends that a thorough conversation regarding lung cancer screening advantages, limitations, known harms, and potential harms between the patient and provider occur prior to initiation of screening (Moyer, 2014). The CMS (2016) require more thorough criteria to be met for reimbursement during a shared decision-making visit that are detailed in Appendix A. Whether these discussions are occurring consistently between patients and providers is not clear.

According to Carter-Harris et al. (2016), their study was the first to provide an evaluation of whether current and former smokers were having discussions with their health care providers about lung cancer screening with LDCT. Carter-Harris et al. (2016) compared the prevalence of lung cancer screening discussions prior to the release of USPSTF guidelines in 2012 to after the publication in 2014. A sample of United States individuals who met criteria for lung cancer screening were surveyed in 2012 and 2014; of 746 surveyed participants in 2012, 17% reported that they had a discussion with their health care provider about lung cancer screening as compared to 10% of 795 surveyed participants in 2014 (Carter-Harris et al., 2016). Participants who were current smokers, who had a family history of cancer, and who had health care coverage were more likely to report having discussions with their provider about screening. This

survey occurred within one year of the publication of the USPSTF guidelines; it has been three years since these participants were surveyed, and it is likely that rates of discussions have increased, but it cannot be substantiated.

Lung cancer screening differs from other cancer screenings because it is largely due to behavior; eighty percent of deaths due to lung cancer have been associated with tobacco smoking (ACS, 2016a). There is a stigma attached to lung cancer as many individuals have labeled it a "smoker's disease" and believe that individuals who develop lung cancer have a personal responsibility for their disease (American Lung Association, 2014). Lung cancer has also been labeled an "invisible cancer" as the onset of symptoms is late, there are poor survival rates, and there is a lack of knowledge (American Lung Association, 2014). In a 2012 survey, the American Lung Association (2014) found that perceived knowledge rates of lung cancer among the public were 9% knew very much, 50% knew something, 30% did not know very much, and 11% knew nothing.

In another survey of 338 individuals who met USPSTF criteria for lung cancer screening with LDCT, attitudes and perceptions about lung cancer were evaluated (Cataldo, 2016). The majority of the sample (82.2%) was concerned about long-term health effects of tobacco smoking; 66% were worried about lung cancer while 75.4% were scared by the thought of lung cancer (Cataldo, 2016). Although the majority of patients perceived concern about lung cancer, only 26.9% of the sample reported that a clinician told them they were at high-risk of developing lung cancer, and 52.1% believed themselves at risk of developing lung cancer (Cataldo, 2016). Over two-thirds of the sample had positive thoughts about LDCT including decreased risk of mortality and improved prognosis with early detection.

Decision aids. Patients and providers both require resources to facilitate this difficult

discussion about screening for lung cancer. As LDCT for lung cancer screening is relatively new and has its risks, a shared decision is necessary and recommended by the USPSTF and CMS. Few decision aids have been created to assist patients and providers with opting to undergo lung cancer screening with LDCT. Decision aids educate patients about their options and allow them to make their own informed decision. Decision aids for patients "significantly improve knowledge, result in more accurate risk perceptions, help patients become more assured about their decisions, decrease passive participation in decision making, and result in decisions consistent with patients' values" (Volk et al., 2014, p. 61). One decision aid in the literature was designed to educate patients with a six-minute video at the eighth grade reading level that included content on lung cancer, its risk factors, a patient undergoing a LDCT scan, and benefits and harms of screening (Volk et al., 2014). Of the 52 participants who viewed the video, 78.8% reported that they were more interested in lung cancer screening, and knowledge regarding lung cancer increased from 25.5% pre-video to 74.8% post-video ($p < .01$). The majority of participants reported that they were clear about what screening benefits mattered most and what harms mattered most (94.1% vs. 86.5%, respectively) (Volk et al., 2014).

In contrast, Lau et al. (2015) used an online decision aid in a sample of current and former smokers aged 45 to 80 years old with no prior history of lung cancer and no chest CT scan within the past year. The decision aid included content on benefits and harms of screening, false-positive rate, follow-up testing, over-diagnosis, and radiation exposure. Sixty individuals were sampled between August 2014 and December 2014 using a pre-test and post-test design. Lau et al. (2015) found that knowledge regarding lung cancer increased overall after viewing the decision aid ($p < .001$), and the mean overall Decisional Conflict Scale scores decreased from 46.33 to 15.08, indicating less conflict ($p < .001$). Concordance scores increased from 14

(23.73%) pre-decision aid to 35 (59.32%) post-decision aid ($p < .001$); concordance was characterized by individuals who were eligible to be screened and preferred to get screened, and individuals who were not eligible to be screened preferred not to get screened. Among individuals who were not eligible for screening, perceptions about lung cancer screening benefits decreased significantly, perceived screening harms increased, and those who would get screened if it were free decreased ($p < .001$). In addition, 76% of the sample thought the information was balanced, and 82% reported that there was enough information to help them make a decision regarding screening.

Lau et al.'s (2015) study was limited in that there was a small sample size and a lack of an explanation for why patients would choose not to get screened even it were free. Based on the results, it could be assumed that those patients preferred not to get screened based on perceived harms and perceived benefits of screening as those numbers increased and decreased, respectively. This study demonstrates the variation in perceptions of lung cancer screening with LDCT after viewing an educational video. Lau et al.'s (2015) findings support the importance of using a decision aid and having a discussion between the patient and provider as each choice to be screened is individualized and based on the patient's values and beliefs.

As there are few evidence-based lung cancer screening decision aids available in the literature, it is difficult to determine what information should be included and how it should be presented. The decision aid in Volk et al.'s (2014) study requires a television or computer and time to view the video, while Lau et al.'s (2015) study requires a computer and internet access to view the content. It would be difficult to plan ahead for a visit like this and plan ahead for a discussion regarding lung cancer screening. Lau et al. (2015) and Volk et al. (2014) both found that knowledge about lung cancer increased significantly after viewing the decision aid, and that

participants were better able to make a decision regarding lung cancer screening. As CMS requires specific criteria and topics to be discussed prior to the initiation of screening with the use of a decision aid, one that would be feasible in primary care practice is necessary.

A paper decision aid to guide these discussions and one that the patient can keep would be ideal to utilize in primary care. All of the topics required by the CMS should be included in the decision aid. The patient should be encouraged to ask questions during the visit to make an informed, shared decision with the provider. Screening individuals who meet eligibility criteria in primary care and other established facilities with access to lung cancer screening and treatment centers is essential to reduce mortality from lung cancer. Additional resources to assist the provider in educating and screening their patients at high risk for lung cancer would be beneficial. Based on this integrative review of the literature regarding lung cancer screening and decision aids, a DNP project was created and implemented. A lung cancer screening toolkit was created, including a paper decision aid, to assist providers in initiating discussions with high-risk current and former adult smokers regarding lung cancer screening.

Theoretical Framework

Havelock's (1976) Theory of Planned Change was utilized for this clinical project to guide provider change within a primary care practice (Appendix B). The Theory of Planned Change was a modified form of Lewin's (1951) Force Field Analysis Theory to best provide a framework for change in the work setting (White & Dudley-Brown, 2012). White and Dudley-Brown (2012) describe the model in their book, *Translation of Evidence Into Nursing and Health Care Practice.* There are seven total steps that are necessary for change. These steps include Care, Relate, Examine, Acquire, Try, Extend, and Review. Stage Zero, Care, highlights the importance for the need for change. For this project, evidence for lung cancer mortality statistics

and high rates of late stage diagnosis indicated the need for change in clinical screening. This problem was identified in the literature and indicated the need for 100% compliance with lung cancer screening. During Stage One, Relate, a relationship was built; this was considered the pre-contemplation phase (Bright Hub Project Management, 2012). A primary care practice in need of an educational intervention on lung cancer screening was identified, and a relationship was built with stakeholders, specifically the Medical Director and office manager.

Stage Two, Examine, assessed and determined the need for change. During this stage, the DNP student worked with stakeholders to assess current practice and the need for change. This was considered the contemplation phase; the relationship could have terminated at this stage if stakeholders did not desire change or see a need for change (Bright Hub Project Management, 2012). However, a lack of knowledge regarding lung cancer screening was identified, and the relationship continued. During Stage Three, Acquire, resources for change were obtained. This stage occurred when data from the integrative review and pre-implementation survey was analyzed and utilized for a lung cancer screening toolkit. Stage Four, Try, included the selection of a solution for change. For this project, a PowerPoint to educate providers on lung cancer screening and a decision aid and toolkit with resources were selected and created.

During Stage Five, Extend, the change was implemented into routine, every day practice and accepted. The DNP student educated primary care providers about lung cancer, lung cancer screening, the decision aid, and the toolkit. Providers gave feedback to the DNP student by completing a survey to enhance the decision aid and toolkit. Providers were asked to use the decision aid and toolkit in practice with patients. Like other individuals, providers may be resistant to change; it is important to focus on this stage and ensure that providers are in agreement with the toolkit's content and ease of use.

The final stage, Renew, was characterized by maintaining the change. After being encouraged to use the toolkit and decision aid in practice over a two month period, providers were administered a final survey to address benefits and barriers to use of the decision aid and toolkit. Providers were encouraged to maintain the change by incorporating the decision aid and toolkit into every day practice; the change agent, the DNP student, separated from the organization and allowed the primary care providers and stakeholders to sustain the change independently. This theory included several steps and addressed multiple factors that were necessary for change to occur. Change can be difficult to incorporate into practice and sustain. Following these steps by identifying the problem and need for change, in addition to ensuring that stakeholders are aware of the deficit and desire the change, enhances the likelihood of sustainability.

Project Design and Methods

This project was an educational intervention designed to translate evidence supporting the need for lung cancer screening with LDCT into clinical practice. Providers were educated using a PowerPoint presentation that focused on increasing awareness and knowledge of lung cancer screening. The PowerPoint included statistics and information on lung cancer, USPSTF guidelines, CMS requirements, literature review findings on LDCT, literature on decision aids for lung cancer, nodule management with the Lung CT Screening Reporting and Data System (Lung-RADS), primary care role, and presentation of the decision aid and toolkit.

A paper decision aid was created for primary care providers to use with their patients to facilitate a discussion about lung cancer screening. The decision aid included information about lung cancer and its statistics, the purpose of screening, importance of adhering to annual screening, eligibility, impact of comorbidities, benefits and risks of screening, follow-up

diagnostic testing, over-diagnosis, false positive rates, radiation risk, and smoking cessation. CMS requirements were incorporated into the decision aid as many of the individuals who meet USPSTF eligibility criteria for lung cancer screening are Medicare eligible. It benefits the provider as CMS requirements are met, and benefits the patient as he/she is able to take the decision aid home as a reference.

The toolkit included multiple varied resources for the provider about lung cancer screening. Resources were included from verified organizations including the Agency for Healthcare Research and Quality, ACS, American College of Radiology, Centers for Disease Control and Prevention, CMS, Lung Cancer Alliance, and USPSTF. The DNP student searched these websites and the internet for valuable information for the provider. These resources included information about CMS requirements, organization recommendations, lung cancer screening program information, Lung-RADS, patient handouts, resources websites, and smoking cessation information. The PowerPoint, decision aid, and toolkit are presented in Appendix C.

Setting and Resources

The clinical settings for this project were two family practices in Waltham and Weston, Massachusetts, which were both located within Middlesex County. Middlesex County has a primarily Caucasian population with 80.1% of the estimated 1,570,315 population being Caucasian (U.S. Census Bureau, 2015; U.S. Census Bureau, n.d.). The majority of the population (96.3%) was estimated to have health insurance coverage; there was estimated to be 81.6% with private health insurance, and 26.1% with public health insurance (U.S. Census Bureau, n.d.). In 2012, there was an estimated smoking prevalence of 14.8% in females and 16.9% in males (Institute for Health Metrics and Evaluation, 2015). The patient population for this project was males and females aged 55 to 80 years old who were current smokers or former

smokers who quit within the past 15 years with at least a 30 pack-year history of smoking. These are the criteria that are recommended for lung cancer screening by the USPSTF.

Description of the group, population, or community. The provider population that was included in this clinical project consisted of primary care providers who cared for adults aged 55 to 80 years old who were at high-risk of developing lung cancer. Participants included six physicians and two nurse practitioners. All were Caucasian, and ages ranged between 30 and 60 years. Two were male, and six were female. At these practices, nurse practitioners conducted sick and follow-up visits, as well as occasional wellness examinations.

Facilitators and barriers. Potential barriers and facilitators were assessed and reevaluated post-educational intervention by the DNP student. For providers, potential barriers to utilizing the toolkit included provider resistance to change and current practice, time constraints, and lack of agreement with guidelines. According to a study in North Carolina of providers' knowledge of lung cancer screening guidelines, 53% knew less than three of the six components of screening, and 25% did not know any components (Barton, 2015). Perceived barriers included harm from false-positives (83%), lack of awareness by patients (81%), lack of insurance coverage (80%), and patient cost (87%) (Barton, 2015). As providers were implementing the guideline recommendations and using the toolkit, it was essential to get a thorough history from them regarding their concerns; this was assessed in the surveys, which is detailed in Appendix D. Potential facilitators included provider belief that LDCT is effective, knowledge of USPSTF lung cancer screening guidelines, desire for improvement, and current practices of screening for smoking history in primary care.

For patients, potential barriers to use of the decision aid included patient resistance, time constraints, and illiteracy. Barriers to having a discussion regarding screening included fear of

having cancer, not wanting to know they have cancer, and patient values. Facilitators to utilizing the decision aid included availability, ease of use, and patient willingness to take an informational packet. Facilitators to patients having a discussion with their provider regarding screening included trust, perceived knowledge and expertise of the provider, and interest in getting screened.

Barriers to receiving a LDCT scan included access to a CT scanner, the patient's ability to travel to get a CT scan, concerns regarding additional testing, and lack of knowledge. Facilitators to obtaining a LDCT scan for lung cancer screening included presence of CT scanners within the hospital, radiologists who are trained and knowledgeable regarding interpretation of chest CT scans, and high rates of health insurance in Middlesex County (96.3%) (U.S. Census Bureau, n.d.). Among a telephone survey of United States adults, 78.5% of current smokers and 81.4% of former smokers stated that they would agree to a CT scan if their doctor recommended it (Delmerico, Hyland, Celestino, Reid, & Cummings, 2014). For those who responded no, the most common reasons were lack of insurance and not wanting to find out if they had cancer (Delmerico et al., 2014).

Goals and Objectives

Table 1

Goals and Objectives

	Goals	Objectives
1	To increase knowledge of lung cancer screening with LDCT in primary care providers.	• Providers will be educated regarding lung cancer screening guidelines and the literature basis; they will be provided with a decision aid and toolkit with educational resources. • Providers will report increased knowledge regarding lung cancer screening practices with LDCT after viewing the PowerPoint presentation and toolkit. • Providers will report an understanding of USPSTF and CMS eligibility criteria for lung cancer screening. • Providers will give feedback regarding the educational

		content of the toolkit and provide areas for improvement.
2	To improve ease of discussions regarding lung cancer screening between primary care providers and patients at high-risk of lung cancer.	• Providers will be educated regarding the importance of having a discussion regarding screening with their patients at high-risk for lung cancer and encouraged to use the decision aid to guide discussions. • Providers will be educated regarding the importance of forming a shared decision regarding screening with the patient. • Providers will give feedback to the DNP student regarding benefits, barriers, and areas for improvement of the toolkit and how it can be used effectively in primary care. • Providers will report benefits, barriers, and areas for improvement of the decision aid and how it can be used effectively in primary care.
3	To increase rates of discussions between patients and providers regarding lung cancer screening with LDCT.	• Providers will be educated regarding the importance of lung cancer screening and encouraged to use the decision aid to have a discussion regarding screening with their patients at high-risk for developing lung cancer. • Providers will be educated regarding the importance of creating a shared decision regarding screening with the patient. • Providers will report how many times the decision aid was utilized with their patients to discuss lung cancer screening. • The number of referrals for lung cancer screening will be compared pre-educational intervention and two months post-educational intervention.
4	To increase rates of referrals for LDCT for lung cancer screening in high-risk, eligible patients.	• Providers will be educated regarding the importance of lung cancer screening and encouraged to refer their patients at high-risk of developing lung cancer to receive annual LDCT. • The number of referrals for lung cancer screening will be compared pre-educational intervention and two months post-educational intervention.
5	To increase patient knowledge of lung cancer screening with LDCT.	• Providers will be educated regarding the importance of discussing lung cancer screening with patients and the importance of forming a shared decision to receive annual LDCT. • Providers will report acceptability of the lung cancer screening decision aid by patients. • Providers will report barriers for use of the decision aid with patients.

Implementation Summary: Presentation and Toolkit

Based on research evidence and recommendations and requirements from the ACS, CMS, and USPSTF, a lung cancer screening decision aid and toolkit, intended for use by primary care providers, was created. A toolkit was created for both primary care offices, with multiple copies of the decision aid provided. Some providers split their time between the two locations, while other providers worked primarily at one location. To evaluate the educational intervention and resources, three surveys were administered, which are summarized in Table 2.

Table 2

Implementation Phases

Phase	Pre-Implementation Survey	Immediate Post-Educational Intervention Survey	Two-Month Post-Educational Intervention Survey
Date Sent Out	11/06/2016	12/04/2016	03/07/2017
Number of Participants	8 of 8	5 of 8	6 of 8
Number of Questions	14	20	19
Goals	To identify frequency of referrals for lung cancer screening, current knowledge and practices regarding lung cancer screening guidelines, barriers to screening, and resources utilized.	To obtain information on benefits, barriers, and areas for improvement of the PowerPoint, decision aid, and toolkit. To determine if knowledge improved post-educational intervention.	To determine if the toolkit and decision aid were useful, if patients accepted the decision aid, and if awareness of lung cancer screening improved.

To achieve goal one, to increase knowledge of lung cancer screening with LDCT in primary care providers, eight providers received education regarding screening. Prior to the educational intervention, an assessment of current knowledge and practices was completed using

a survey and talking with the Medical Director and office manager. After conducting the pre-assessment, providers were educated with a PowerPoint presentation and provided with the decision aid and toolkit. Time was allotted for questions and discussion between the DNP student and providers. An immediate post-educational intervention survey was administered to determine if providers felt more knowledgeable about lung cancer screening, if the content was useful, and how the content could be improved. All online surveys were sent to providers via email. The surveys included statements with Likert-Scale responses, questions with numerical responses, and open-ended questions. Findings from the immediate survey were reviewed by the DNP student, and the toolkit and decision aid were altered to reflect the suggestions of the providers.

To achieve goal two, to improve ease of discussions regarding lung cancer screening between primary care providers and patients at high-risk of lung cancer, a decision aid and toolkit were created. The decision aid was designed to be used as a guide during discussions about screening with patients at high-risk for developing lung cancer, while the toolkit was designed to be used as a resource for providers. Providers were given the revised decision aid and toolkit, and encouraged to utilize them with patients at high-risk of developing lung cancer over a two-month period; this was the implementation phase. Additionally, two months later, a final survey was administered to determine ease of discussions about screening and patient acceptability of the decision aid.

To achieve goal three, to increase rates of discussions between patients and providers regarding lung cancer screening with LDCT, facilitators and barriers to having a discussion were assessed prior to the educational intervention. After the educational intervention, providers were asked how the toolkit and decision aid could be improved; tailoring resources to the providers'

needs could enhance knowledge and use. The number of referrals for lung cancer screening were assessed at each survey and compared. At the final survey, providers were asked how many times they used the decision aid and toolkit over the implementation period. Benefits and barriers to their use were addressed at the immediate and two-month post-educational intervention surveys.

To achieve goal four, to increase rates of referrals for LDCT for lung cancer screening in high-risk, eligible patients, providers were educated regarding the importance of screening and compliance with USPSTF guidelines, and encouraged to refer their eligible patients. The final survey addressed frequency of use of the decision aid and toolkit, benefits and disadvantages, and areas for improvement. The number of referrals for lung cancer screening were assessed at each survey and compared.

To achieve goal five, to increase patient knowledge of lung cancer screening with LDCT, providers were educated on the importance of having a meaningful discussion and forming a shared decision with the patient regarding screening for lung cancer. Providers were asked if they thought patients were receptive to the decision aid, and if they found the toolkit helpful to use with their patients. Providers also reported barriers to use of the decision aid with patients at the two-month post-survey. The survey design included numerical responses, statements with Likert-scale responses, and open-ended questions.

Data Analysis

Descriptive statistics were used to analyze the data. All questions, except the final question, required responses; therefore, there were no questions with missing data. For open-ended questions, themes were identified. Benefits, disadvantages, and barriers to use of the decision aid, PowerPoint, and toolkit were identified. Frequency of referrals for lung cancer

screening and frequency of use of the decision aid and toolkit were quantified. Data was entered into Excel and organized. Survey results are presented in Appendix D.

Results

Pre-implementation survey. The first survey was used to identify frequency of referrals for lung cancer screening, current knowledge and practices regarding lung cancer screening guidelines, barriers to screening, and resources utilized. All eight providers responded to this survey. Four providers agreed that they were aware of lung cancer screening guidelines, and four providers strongly agreed. Responses regarding awareness of CMS requirements for a shared decision-making visit for lung cancer screening varied; two of eight providers strongly agreed that they were aware of CMS requirements, two agreed, three were neutral, and one disagreed. Furthermore, two of eight providers strongly agreed, five were neutral, and one disagreed that they met all of the required aspects for a shared decision-making visit with Medicare patients. These results highlighted that there was a need for education regarding guidelines, specifically the CMS requirements. All eight providers identified education that would be helpful regarding lung cancer and screening. Responses included anything, a review of the guidelines, Medicare guidelines education, other, patient handout, presentation, statistics, tool on Epic, and videos.

Referrals for lung cancer screening were low; no referrals were made within the past week of sending the survey, and only two providers reported making one to two referrals over the past month. Seven of eight providers reported that they had missed referring a patient for LDCT. Four of eight providers agreed that they find it easy to have discussions about lung cancer screening with patients, while four providers felt neutral. Factors identified as contributing to patients not being referred for LDCT included time (3 of 8 providers), pack-year

history not documented (2 of 8), pack-year history not assessed during the visit (2 of 8), patient refusal (4 of 8), and other (2 of 8). One provider identified other factors including a non-compliant patient population with many unaddressed needs that were of a higher acuity, and difficulties with the Epic system being poorly designed and not providing adequate clinical care reminders.

Barriers to referring patients for LDCT were categorized into patient barriers and system barriers; seven of eight providers reported that there were barriers to referral. Patient barriers included health care literacy, lack of interest, patient acceptance, and the visit not being related to smoking. System barriers included disregard of primary care physician's time by administration and specialists, insurance coverage, lack of adequate clinical support, not having all information required to order a LDCT scan, and a poor Epic system. Barriers to educating patients regarding lung cancer screening were assessed. Seven of eight providers reported that there were barriers, with three providers identifying time as a barrier. Other barriers included awareness, education materials that are easily accessible and easily understood, handouts, knowledge of the workup after a positive screen, and videos; one provider reported there were no barriers to education.

Six of eight providers reported that there were resources that they have and use for lung cancer while two providers reported there were no resources. Of the six providers who identified resources, these included DOT phrases, Dynamed, Google, handouts, the internet, Primary Care Office InSite (PCOI), smoking history, and UpToDate. One provider reported that there were very little resources. All eight providers identified resources that would be helpful; these included handouts, Lung Cancer Association algorithm, and printed guidelines. Three providers felt that an improved Epic system would be helpful including smart phrases with all talking points, and follow-up questions to alert the provider to order the test if there is a positive

smoking history. Finally, one provider reported that it would be helpful if pulmonologists had a more proactive approach with lung cancer screening to reduce the burden on primary care providers.

Immediate post-educational intervention survey. The second survey was administered four days after providers received the educational intervention. Four of the eight providers were able to attend the presentation in person. All providers were emailed the PowerPoint, asked to review it if they did not attend the presentation, and asked to complete the survey. Five out of eight providers completed the second survey which was intended to obtain information on benefits, barriers, and areas for improvement of the PowerPoint, decision aid, and toolkit.

The results indicated that only one provider made a referral for LDCT during the week prior to the survey, and two providers made between one and two referrals for LDCT during the month prior to the survey. Four of five providers agreed that the PowerPoint was useful and would be beneficial to practice, while one provider strongly agreed. Knowledge about lung cancer screening improved post-presentation; all five providers agreed that they felt more knowledgeable about lung cancer screening after viewing the PowerPoint.

Five of five providers reported what they liked about the PowerPoint, while three of five providers reported how it could be improved. Providers reported that the PowerPoint was brief, clear, concise, and detailed; others reported that it provided important information, statistics, and benefits and harms of screening. Providers suggested that the PowerPoint could be improved by adding statistics including numbers needed to treat, numbers needed to harm, and biopsies and stress from incidental findings and benign pulmonary lesions; one provider thought that the presentation could have been more interactive and shorter. Providers were emailed the number needed to treat and number needed to harm values, and this information was added to the toolkit.

All five providers felt that the decision aid would increase patient knowledge of lung cancer screening and was easy to read, but there were concerns about implementing it into practice. Four providers agreed and one provider strongly agreed that the decision aid would increase patient knowledge of lung cancer screening and would allow the patient to make an informed decision about screening. All five providers agreed that the decision aid was easy to read. One provider strongly agreed, three agreed, and one felt neutral about the decision aid helping the provider discuss lung cancer screening with patients. One provider strongly agreed, two agreed, and two felt neutral about the decision aid being easy to incorporate into practice. Five of five providers reported what they liked about the decision aid; providers liked that the decision aid was straightforward for patients, easy to read and understand, easy to use, and included good information. Four of five providers did not feel that the decision aid needed to be improved; one provider thought that it could be more basic, include information for low literacy patients, and have pictures.

Three of five providers were able to view the toolkit; of those three providers, all three agreed that content in the toolkit was useful and would be easy to incorporate into practice. Three providers reported what they liked about the toolkit. One provider felt that the toolkit was a good resource, one provider liked its ease of use, and another provider reported that it contained information that was easy to read for the patient. Of the three providers that viewed the toolkit, two felt that it did not need to be improved, while one provider felt that additional websites could be added.

Two-month post-educational intervention survey. The final survey was administered after the two-month implementation phase. Six of eight providers completed the final survey which was designed to determine if the toolkit and decision aid were useful, if patients accepted

the decision aid, and if awareness of lung cancer screening improved. Four providers agreed and two strongly agreed that they felt more aware of USPSTF guidelines. Four providers felt more knowledgeable about lung cancer screening, while one provider strongly agreed, and one felt neutral. No referrals for lung cancer screening were made over the week before the survey; over the month before the survey, one to two referrals were made by one provider.

The decision aid was used by two out of six providers over the two-month implementation period. Of the providers that used the decision aid, one strongly agreed and one felt neutral about the decision aid increasing patient knowledge of lung cancer and screening; these two providers agreed that the decision aid allowed the patient to make an informed decision about screening for lung cancer and that the decision aid was easy to read. These two providers felt that their patients accepted the decision aid; one provider strongly agreed and one agreed that the decision aid helped them to discuss lung cancer screening with patients and that the decision aid was easy to incorporate into practice. Of the providers that used the decision aid with patients, reported benefits included that it was something that the patient could take home and look at, and that the discussion was laid out. Barriers included that it was time consuming and that it may be too burdensome for the patient to make the decision to be screened for lung cancer. The remaining four providers answered questions about the decision aid, although they reported that they did not use it during the implementation period; their responses are detailed in Appendix D.

Over the two-month implementation period, one provider reported that he/she used the toolkit two to three times, while five providers did not use the toolkit. The provider that used the toolkit agreed that the toolkit was useful and was easy to incorporate into practice. This provider reported that the toolkit directed the discussion, but a barrier to its use was that it was time

consuming. The remaining five providers answered questions about the toolkit, although they reported that they did not use it during the implementation period; their responses are detailed in Appendix D.

Discussion

All eight providers responded to the first survey, while five and six providers completed the immediate and two-month post-educational intervention surveys, respectively. All responses were anonymous, and it is unknown if the same providers did not respond to the post-educational intervention surveys. Referrals for lung cancer screening did not improve post-implementation. This may be due to the fact that over a short, two-month implementation period, providers did not see enough patients with a positive smoking history, or coordinate follow-up for this discussion within the time frame. Over a longer period of time, it is hoped that more patients who meet USPSTF criteria will be identified, and more discussions and referrals for lung cancer screening will be made.

The first survey assisted the DNP student in identifying potential barriers to having discussions regarding lung cancer screening with patients and referring patients for LDCT. Patient refusal (4 of 8 providers) and time (3 of 8 providers) were the most frequently reported responses for why patients do not get referred for LDCT. In addition to barriers being identified, a lack of education regarding CMS requirements and USPSTF guidelines was identified; this aided the DNP student in tailoring education and resources to the providers' needs.

The second survey focused on benefits, disadvantages, and areas for improvement of the PowerPoint, decision aid, and toolkit. The PowerPoint content was beneficial and useful and increased knowledge regarding lung cancer screening. The decision aid was perceived well, but not all providers felt that it could be easily incorporated into practice. At the final survey, the

decision aid was still perceived as beneficial due to the discussion being laid out and the patient being able to take the decision aid home, but time and patient burden with making the decision to be screened for lung cancer were barriers to its use. Due to the length of the conversation regarding lung cancer screening, it would be beneficial for patients to be brought in for a follow-up appointment to discuss screening to allow for adequate time and questions. Although many patients still feel that their provider is correct and should make all the recommendations, health care has changed. Patient-centered care is promoted, and the patient's values and beliefs should be incorporated into the shared decision between the patient/family and provider. The provider's role is to educate and guide the patient to health and well-being. Finally, with the risks associated with screening, it is important to thoroughly discuss risks versus benefits, consider comorbidities, and form a shared decision with the patient.

Although the majority of providers reported not using the Toolkit over the two-month implementation period, four providers agreed that the content was useful, while two providers were neutral; the one provider that used the toolkit in practice agreed that the content was useful. Its incorporation into practice may have been difficult; the number of providers that agreed that it would be easy to incorporate into practice remained stable from survey two to survey three; at survey three, the only provider that incorporated the toolkit in practice agreed that it was easy to do this. Barriers to its use included patient receptiveness and time. These themes remained constant throughout the surveys. Conversations regarding screening for lung cancer need to occur, but finding the time and approach is difficult. The educational intervention and presentation of the decision aid and toolkit created awareness and provided resources to the primary care providers. With time, adequate resources, and increased awareness, providers can better identify patients who meet criteria, schedule a follow-up visit to discuss screening, and

refer eligible patients for LDCT.

This DNP project is difficult to compare to other studies in the literature. A search of the literature did not identify any study incorporating and evaluating provider education regarding lung cancer screening. There are studies that address provider perception of lung cancer screening guidelines, but education and resources to increase referral rates were not provided (Duong et al., 2017; Klabunde et al., 2010; Lewis et al., 2015). Another study, discussed previously, compared rates of discussions about lung cancer screening before and after the release of the USPSTF guidelines in 2013; but, this study looked at the patient perspective only (Carter-Harris et al., 2016). Finally, two studies evaluated the effectiveness of an online and video decision aid for lung cancer screening; again, this study looked at the patient perspective and was discussed previously (Lau et al., 2015; Volk et al. 2014).

Limitations. This project had its limitations. The sample size was small, and not all providers responded to all surveys. A discrepancy was noted in the final survey. Only two of six providers reported that they used the decision aid over the past two months, but three providers reported in a later question that they used the decision aid and their patients accepted the aid. It is unclear if one provider did not respond appropriately to the first question, or if they misread the later question. This could also be accounted for by the survey design, as most questions were required to be answered, and there was not an option "not applicable" in all questions. The DNP student did not have any interaction with patients, and their thoughts regarding the decision aid were not elicited directly. Obtaining their thoughts directly may determine how to best approach the discussion from a provider perspective. Further research regarding the patient perspective is indicated.

Ethics and Human Subjects Protection

The University Institutional Review Board (IRB) reviewed the project proposal and determined that it did not involve human subjects research; therefore, this project was exempt from further review. This DNP project did not include any interaction with patients; the DNP student only interacted with primary care providers. No patient health information was obtained or reviewed; the Health Insurance Portability and Accountability Act (HIPAA) of 1996 was maintained as patient health information was protected and maintained as private (Health and Human Services Department, 2013). The *Standards of Care* for practice in a primary care office was utilized by the DNP student and primary care providers during this project. The providers who completed the survey and offered information and feedback regarding the lung cancer screening toolkit remained anonymous and did not have their statements connected to their name. The DNP student kept this information private and utilized it for the DNP project only. The IRB determination form is presented in Appendix E.

Conclusion

Deaths due to lung cancer account for one out of four cancer deaths in the United States (ACS, 2016a). Lung cancer screening with annual LDCT has been shown in the literature to reduce lung cancer mortality and all-cause mortality, and improve rates of early stage diagnosis of lung cancer. In the NLST, the National Lung Screening Trial Research Team (2011) provided promising, statistically significant results including a relative reduction in lung cancer mortality of 20% with LDCT (95% CI, 6.8-26.7; $p = .004$) (The National Lung Screening Trial Research Team, 2011). The USPSTF, among other organizations, supports the use of annual LDCT for high-risk current and former adult smokers and recommends shared decision-making between the patient and provider. This DNP project was designed to improve rates of lung cancer

screening and ultimately reduce lung cancer mortality rates by increasing provider and patient knowledge of lung cancer and screening. The results indicate that the decision aid and toolkit may be beneficial to practice, but provider time and patient receptiveness were barriers to their use. Further research is indicated to identify how to effectively educate and refer patients for screening.

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Appendix A

Requirements for CMS

For coverage of lung cancer screening with LDCT, the Medicare beneficiary must meet ALL of the following criteria:

- Age 55-77 years old
- No signs or symptoms of lung cancer
- At least a 30 pack-year history of smoking
- Current smoker or former smoker who quit within the past 15 years
- Have an order for lung cancer screening that meets National Coverage Determination (NCD) requirements

The order for lung cancer screening with LDCT must include ALL of the following information regarding the beneficiary:

- Date of birth
- Pack-year history of smoking
- Smoking status; if a 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)

Before the LDCT scan occurs for lung cancer screening, a lung cancer screening counseling and shared decision-making visit must occur where the order is written; the following elements must be met and documented:

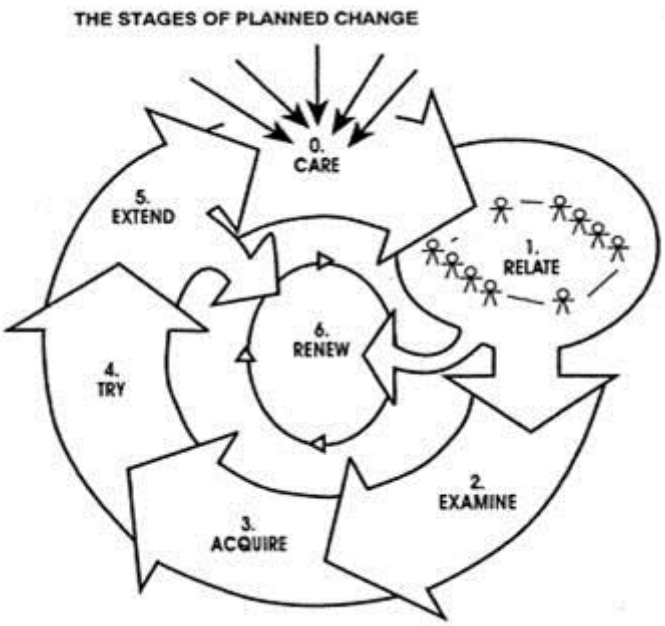
- Must be furnished by a physician or qualified non-physician practitioner (Physician Assistant, Nurse Practitioner, Clinical Nurse Specialist)
- Determination of beneficiary eligibility for screening include age, lack of signs or symptoms of lung cancer, pack-year history of smoking, and number of years since cessation, if a former smoker.
- Shared decision-making, with the use of one or more decision aids, including benefits and harms of screening, follow-up diagnostic testing, over-diagnosis, false positive rate, and total radiation exposure must be included.
- Counseling regarding the importance of adhering to annual lung cancer screening with LDCT, comorbidities impact, and ability/willingness to be diagnosed and treated
- Counseling regarding the importance of smoking cessation for current and former smokers; if beneficiary is a current smoker, information is provided about smoking cessation interventions, if appropriate
- The furnishing of a written order for LDCT for lung cancer screening, if appropriate

The reading radiologist and the radiology imaging facility also have specific criteria that must be met.

(Centers for Medicare and Medicaid Services, 2016)

Appendix B

Havelock's (1974) Theory of Planned Change



(Havelock, 1974, as cited in Dalton, Hrubik-Vulanovic, & Wahoff, 2009)

Appendix C

Lung Cancer Screening Decision Aid, PowerPoint, and Toolkit

Lung Cancer Screening Decision Aid

Lung Cancer Screening 2016

A Guide for Patients about Lung Cancer Screening*

What is Lung Cancer?

Lung cancer is the #1 cause of death from cancer in both men and women; 1 out of 4 deaths from cancer are due to lung cancer. The 5-year survival rate is 17.8% and is lower than many other cancers. If lung cancer is found early, survival rates can increase to 54%. But, only 15% of lung cancer cancers are found early.

Who Gets Lung Cancer?

Smoking is the #1 cause of lung cancer, accounting for 80% of deaths from lung cancer. 2 out of 3 persons who get lung cancer are 65 years and older. 1 in 14 males develop lung cancer, while 1 in 17 women develop lung cancer.

How Can You Reduce Your Risk of Getting Lung Cancer?

Quit smoking, if you currently smoke.

Get screened annually; keep follow-up appointments/tests as recommended by your provider.

What is Lung Cancer Screening?

Lung cancer screening uses a low-dose computed tomography (CT) scan to find nodules in your lungs. Research has shown that

these CT scans are able to find lung cancer at an earlier stage and reduce the risk of dying from lung cancer.

Who is Eligible to Be Screened?

Those who qualify for lung cancer screening include individuals:

- Aged 55-80 years old
- Who currently smoke or who have quit within the past 15 years; and
- Who have smoked 30 pack-years or more

A pack-year helps to define how many cigarettes you have smoked your life. It is measured by multiplying the number of packs per day by the number of years smoked. If you smoked 2 packs per day for 15 years, you would have smoked 30 pack-years.

If you have another condition that limits your life expectancy, lung cancer screening may not be for you. Talk with your provider.

If you have Medicare, lung cancer screening is for persons up to age 77.

What Happens During A CT Scan?

You will lay flat on an exam table, likely with your arms over your head. You will hold your breath for 5-10 seconds while the table moves through the CT scanner.

What Happens After the CT Scan?

The CT scan will be reviewed by a radiologist and your provider. If a lung nodule is found, you may need a follow-up scan in 6

months to 1 year to see if the nodule is growing. If the nodule grows, your provider may recommend a PET scan or a biopsy. Most lung nodules that are found are not cancer, and your provider may continue to recommend annual screening with low-dose CT scans.

What are the Benefits and Harms of Screening?

Benefits	Harms
• Cancer is detected early and improves survival and treatment options from lung cancer • Lower chance of dying from lung cancer; one large study found a 20% reduction in death from lung cancer	• Radiation exposure – It is a very low dose, and uses almost 90% less radiation than a standard chest CT scan • False positives – most lung nodules that are found are **not** cancer; for every nodule that is found to be cancerous, 25 are **not** • Overtreatment – A nodule is found that looks like cancer and treatment is started; but, if treatment did not occur, this nodule would not have caused any problems • Follow-up testing – CT scans cannot diagnose cancer alone; follow-up testing is usually necessary to make a diagnosis • Invasive procedures – A positive CT scan can lead to

	invasive procedures such as a biopsy or surgery; any invasive procedure has risks that range from minor bleeding and infection to a collapsed lung or death

Why Should I Get Screened?

Deciding to get screened for lung cancer should be based on a conversation between you and your provider. There are risks associated with screening that may matter more to you than someone else. But, research has shown that screening once a year for lung cancer has resulted in lung cancer being diagnosed earlier and a reduced risk of dying from lung cancer.

This decision aid was adapted from the University of Michigan's (2016) online decision aid at www.shouldiscreen.com. Go to that website for more information.

*Created by Courtney Cloonan

References:

American Lung Association (n.d.). Lung cancer fact sheet. *Lung Health & Diseases.* Retrieved from http://www.lung.org/lung-health-and-diseases/lung-disease-lookup/lung-cancer/learn-about-lung-cancer/lung-cancer-fact-sheet.html?referrer=http://www.lung.org/search-results.html?q=lung%20cancer

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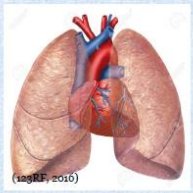
Lung Cancer Screening PowerPoint Presentation Slides



Lung Cancer Screening with LDCT

Courtney Cloonan
UMass Amherst College of Nursing
2016

Lung Cancer Statistics

- Lung cancer is the leading cause of cancer death, accounting for about 25% of cancer mortality
- 2016 U.S. estimates include 224,390 new cases of lung cancer and 158,080 lung cancer deaths
- Non-small cell lung cancer (NSCLC) accounts for 80-85% of lung cancer cases and small cell lung cancer (SCLC) accounts for about 10-15% of cases
- NSCLC Survival Rates by Stage:
  - Stage I: 45-49%
  - Stage II: 30-31%
  - Stage III: 5-14%
  - Stage IV: 1%
- SCLC Survival Rates by Stage:
  - Stage I: 31%
  - Stage II: 19%
  - Stage III: 8%
  - Stage IV: 2%

(American Cancer Society [ACS], 2016a; ACS, 2016b; ACS, 2016c; ACS, 2016d)

Who Gets Lung Cancer?

- Smoking accounts for 80% of lung cancer deaths
- Current and former smokers are both at risk; lung cancer develops over approximately 20 years (Manser et al., 2013)
- 2/3 of persons who develop lung cancer are 65 years and older
- 1 in 14 men and 1 in 17 women develop lung cancer in their lifetime

(ACS, 2016a)

Problem Statement

Risk of mortality from lung cancer among high risk current and former adult smokers is indicated by high lung cancer mortality rates and late stage diagnosis of lung cancer and results from lack of adherence to lung cancer screening guidelines in primary care and/or a lack of knowledge by patients.

Lung Cancer Screening

- The American Cancer Society (ACS) and the United States Preventive Services Task Force (USPSTF) released guidelines recommending annual low-dose computed tomography (LDCT) in high risk current and former adult smokers
- USPSTF Eligibility Criteria:
  - Aged 55-80 years;
  - Current smoker or former smoker who quit within the past 15 years; and
  - 30 pack-year history of smoking or more
- Screening is no longer indicated when it has been 15 years since quit date, or if the person develops a health condition that significantly limits their life expectancy or ability/ willingness to have curative lung surgery

(Moyer, 2014)

Integrative Review of the Literature

- A review of the literature was conducted to determine the effectiveness of LDCT for lung cancer screening
- 7 randomized controlled trials (RCT) and 8 cohorts included
- Studies published from 2000 to 2016
- Participants included males and females aged 50 years and older, current and former smokers
- Outcomes: Lung cancer mortality, all-cause mortality, lung cancer diagnosis and stage

Findings: Lung Cancer Mortality

- The National Lung Screening Trial (NLST), a large RCT, randomized 26,722 participants to the LDCT group and 26,732 to the CXR group; they found a 20% relative reduction in lung cancer mortality with LDCT (95% CI, 6.8-26.7, p = .004) (The National Lung Screening Trial Research Team, 2011)
- Other RCTs, the Detection and Screening of Early Lung Cancer with Novel Imaging Technology (DANTE) study and the Danish Lung Cancer Screening Trial (DLCST), found no differences in lung cancer mortality between screening groups (Saghir et al., 2012; Infante et al., 2015). These studies had much smaller sample sizes: 2,450 and 4,104, respectively
- Two cohort studies reported lung cancer mortality results: 20.59% of 136 deaths were due to lung cancer in Veronesi et al.'s (2014) study, and 23 deaths (38%) were due to lung cancer in Veronesi et al.'s (2013) study

Findings: All-Cause Mortality

- The NLST was the only RCT to find a statistically significant difference in all-cause mortality rates between groups; overall mortality reduction with LDCT of 6.7% (95% CT, 1.2-13.6, p = .02)
- Studies by Becker et al. (2015), Infante et al. (2015), and Saghir et al. (2012) did not have statistically significant findings between groups
- In the cohorts, Veronesi et al. (2013) found 60 total deaths, resulting in a mortality rate of 0.67 per 100 person-years; Veronesi et al. (2014) reported 136 deaths

Findings: Lung Cancer Stage at Diagnosis

- Of the RCTs, three demonstrated statistically significant differences for stage at diagnosis of lung cancer:
  - NLST: Stage I lung cancer diagnosed in 63% of the LDCT group vs. 47.6% in the CXR group (The National Lung Screening Trial Research Team, 2011)
  - DANTE: 47 in the LDCT group, vs. 16 in the control group (p = .0002) (Infante et al., 2015)
  - DLCST: 70% in screening group were early stage (I-IIB) vs. 33% in the control group (Saghir et al., 2012)

Findings: Lung Cancer Stage at Diagnosis

- The majority of lung cancers diagnosed by LDCT in the cohort studies were stage I
  - Roberts et al. (2007): 15 of 19 (78%) NSCLC cases were stage I
  - Wilson et al. (2008): 40 of 69 (58%) NSCLC cases were stage I
  - Menezes et al. (2010): 44 of 65 were stage I
  - Dhopeshwarkar et al. (2011): 55 of 81 (68%) were stage I
  - Greenberg et al. (2012): 26 (79%) were stage I
  - Veronesi et al. (2013): 55 of 71 were stage 1
  - Veronesi et al. (2014) 136 of 175 (78%) were stage I

Findings: Discussion

- Findings for mortality rates were only statistically significant in the NLST; this study had a much larger sample size than other studies
- Other factors to consider: number of annual scans performed, follow-up times, years since smoking cessation
- Majority of studies showed that LDCT was able to diagnose more stage I cancers; Gohagan et al.'s (2005) study did not have statistically significant results, but sample size small. Only 60 lung cancers diagnosed as compared to 2,001 diagnosed in the NLST (The National Screening Trial Research Team, 2011)
- **18,000** lung cancer deaths could be **prevented** each year if lung cancer screening were implemented nationally (Goulart & Ramsey, 2013)

Lung Cancer Screening

- USPSTF recommends annual lung cancer screening with LDCT in high risk current and former smokers
- Lung cancer screening is a Grade B recommendation: "there is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial" (USPSTF, 2016)

Shared Decision-Making

- USPSTF recommends shared decision-making: a discussion regarding lung cancer screening advantages, limitations, known harms, and potential harms between the patient and provider occur prior to initiation of screening
- The CMS (2016) requires a shared decision-making visit for reimbursement with specific criteria

Requirements for CMS

For coverage of lung cancer screening with LDCT, the Medicare beneficiary must meet ALL of the following criteria:

- Age 55-77 years old
- No signs or symptoms of lung cancer
- At least a 30 pack-year history of smoking
- Current smoker or former smoker who quit within the past 15 years
- Have an order for lung cancer screening that meets National Coverage Determination (NCD) requirements

(CMS, 2016)

Requirements for CMS Cont.

The order for lung cancer screening with LDCT must include ALL of the following information regarding the beneficiary:

- Date of birth
- Pack-year history of smoking
- Smoking status; if a 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)

(CMS, 2016)

Requirements for CMS Cont.

Before the LDCT scan occurs for lung cancer screening, a lung cancer screening counseling and shared decision-making visit must occur where the order is written; the following elements must be met and documented:

- Must be furnished by a physician or qualified non-physician practitioner (Physician Assistant, Nurse Practitioner, Clinical Nurse Specialist)
- Determination of beneficiary eligibility for screening include age, lack of signs or symptoms of lung cancer, pack-year history of smoking, and number of years since cessation, if a former smoker.
- Shared decision-making, with the use of one or more decision aids, including benefits and harms of screening, follow-up diagnostic testing, over-diagnosis, false positive rate, and total radiation exposure must be included.

(CMS, 2016)

Requirements for CMS Cont.

Additional elements to be documented during the shared decision-making visit:

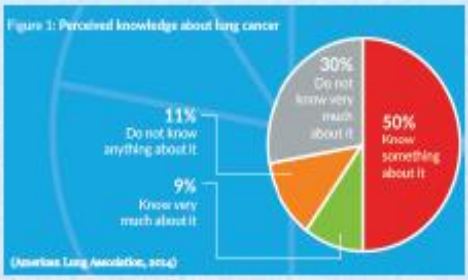
- Counseling regarding the importance of adhering to annual lung cancer screening with LDCT, comorbidities impact, and ability/willingness to be diagnosed and treated
- Counseling regarding the importance of smoking cessation for current and former smokers; if beneficiary is a current smoker, information is provided about smoking cessation interventions, if appropriate
- The furnishing of a written order for LDCT for lung cancer screening, if appropriate

The reading radiologist and the radiology imaging facility also have specific criteria that must be met.

(CMS, 2016)

Lack of Education

- A 2012 evaluated perceived knowledge of lung cancer among that public:



Lung Cancer Perceptions

- In a survey of 338 patients who meet USPSTF criteria for lung cancer screening:
  - 66% were worried about lung cancer
  - 75.4% were scared by the thought of lung cancer
  - 26.9% reported that a clinician told them they were at high risk of developing lung cancer
  - 52.1% believed themselves that they were art risk of developing lung cancer
  - Greater than 2/3 had positive thoughts about LDCT including decreased risk of mortality and improved prognosis with early detection

(Cataldo, 2016)

Decision Aids

- CMS requires the use of a decision aid
- Decision aids for patients "significantly improve knowledge, result in more accurate risk perceptions, help patients become more assured about their decisions, decrease passive participation in decision making, and result in decisions consistent with patients' values" (Volk et al., 2014, p. 61)

(Therapeutic Goods Administration, n.d.)

Decision Aids Cont.

2 decision aids in the literature

- 6 minute video at the 8th grade reading level including info on lung cancer and risk factors, a patient undergoing a LDCT scan, benefits vs. harms, and comparison of benefits vs. harms (Volk et al., 2014)
- Online decision aid including info on benefits vs. harms of screening, false-positive rate, follow-up testing, overdiagnosis, and radiation exposure (Lau et al., 2015)

Decision Aid Findings

Volk et al. (2014)

- Lung cancer knowledge lung cancer increased after viewing the video ($p < .01$)
- 78.8% reported they were more interested in lung cancer screening
- Majority of patients reported they were clear about what screening benefits and harms mattered most (94.1% vs. 86.5%, respectively)

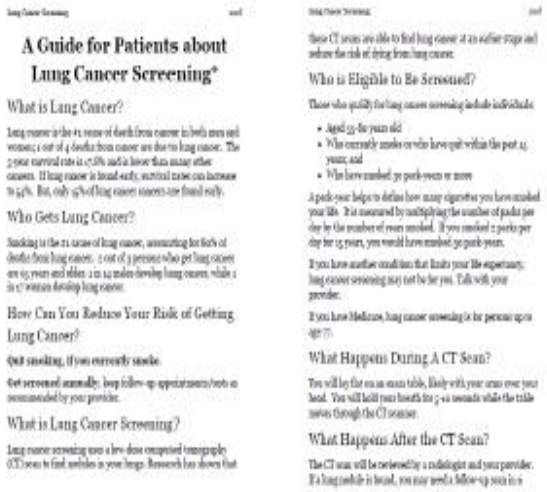
Lau et al. (2015)

- Lung cancer knowledge lung cancer increased after viewing the online aid ($p < .001$)
- Mean overall Decisional Conflict Scale scores decreased from 46.33 to 15.08, indicating less conflict ($p < .001$)
- Concordance scores increased significantly after the aid; concordance characterized by those who were eligible to get screened preferred to get screened and those who were not eligible preferred not to get screened

Paper Decision Aid

- A video or online-based decision aid may be difficult to implement due to TV/internet access, time, and motivation
- A paper-based decision aid would be feasible in primary care
- As a provider, you can use the aid to educate the patient about screening and give the patient the handout to refer to at home
- I have created a paper decision aid to utilize in primary care to promote screening, increase knowledge of lung cancer and screening, and ultimately reduce lung cancer mortality rates and increase rates of earlier stage diagnosis of lung cancer
- After viewing this PowerPoint and the Paper Decision Aid, please fill out a survey to provide your thoughts regarding this aid, and how it can be improved to benefit you and your patients

Thank you!



A Guide for Patients about Lung Cancer Screening*

What is Lung Cancer?

Who Gets Lung Cancer?

How Can You Reduce Your Risk of Getting Lung Cancer?

Quit smoking, if you currently smoke.

Get screened annually: keep follow-up appointments/tests as recommended by your provider.

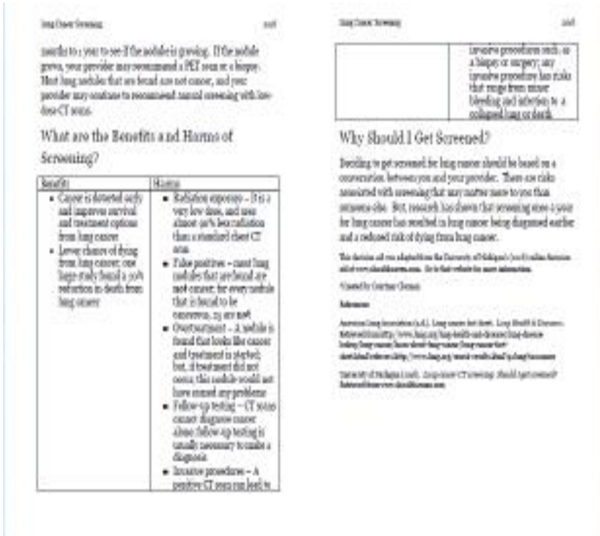
What is Lung Cancer Screening?

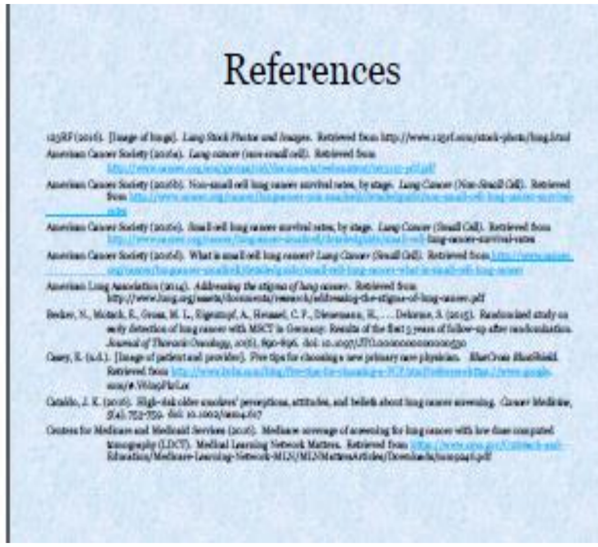
Who is Eligible to Be Screened?

- Aged 55–80 years old
- Who currently smoke or who have quit within the past 15 years; and
- Who have smoked 30 pack-years or more

What Happens During A CT Scan?

What Happens After the CT Scan?


What are the Benefits and Harms of Screening?
Why Should I Get Screened?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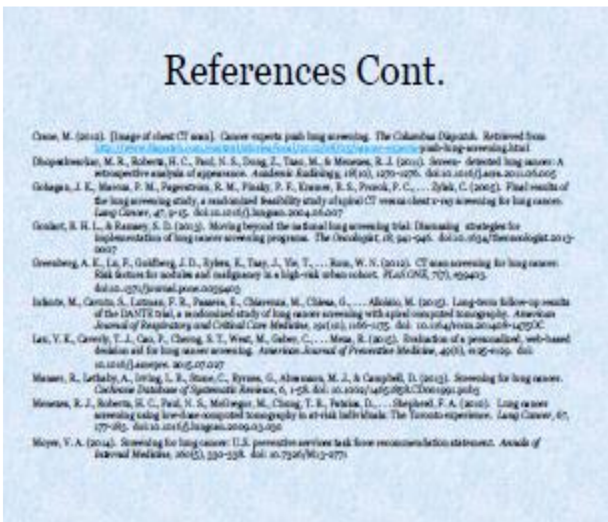
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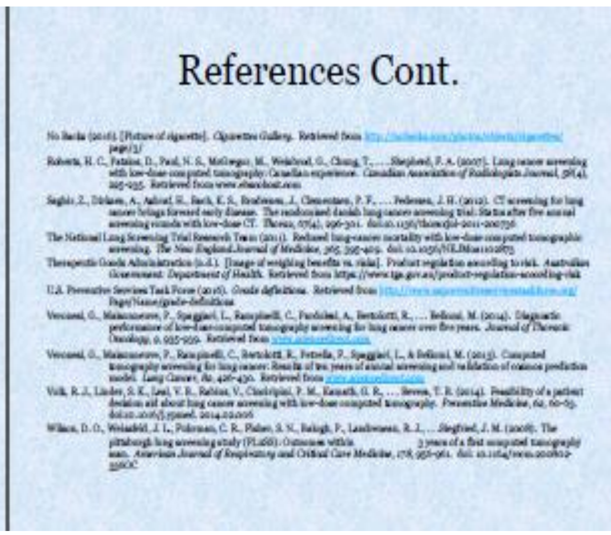
References Cont.

Lung Cancer Screening Toolkit

LUNG CANCER SCREENING TOOLKIT

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University of Massachusetts Amherst
School of Nursing
November 2016

Table of Contents

Lung Cancer Screening Recommendations

Organization:	U.S. Preventive Services Task Force (USPSTF)	Centers for Medicare & Medicaid Services (CMS)
Relevant Group:	Individuals with private health insurance	Medicare beneficiaries
Age in years:	55-80	55-77
Smoking status:	Current smoker or former smoker who quit within the past 15 years	
Lung cancer signs/symptoms:	Asymptomatic	
Screening frequency:	Annually	
When to discontinue screening:	Age limit is exceeded, it has been 15 years since quit date, or the individual develops a health problem that will substantially limit life expectancy or the ability or willingness to have curative lung surgery	

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 smoking history. 2. Long-term lung cancer survivors who have completed 4 years of surveillance without recurrence, and who can tolerate lung cancer treatment in order 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 with ≥ 30 pack-year smoking history, either currently smoking or have quit within the past 15 years, and who are in relatively good health.	2013
American College of Chest Physicians[4]	Age 55 to 74 years with ≥ 30 pack-year smoking history and either continue to smoke or have quit within the past 15 years.	2013
American College of Chest Physicians and American Society of Clinical Oncology[5]	Age 55 to 74 years with ≥ 30 pack-year smoking history and either continue to smoke or have quit within the past 15 years.	2012
American Lung Association[6]	Age 55 to 74 years with ≥ 30 pack-year smoking history and no history of lung cancer.	2012
National Comprehensive Cancer Network[7]	1. Age 55 to74 years with ≥ 30 pack-year smoking history and smoking cessation < 15 years. 2. Age ≥ 50 years and ≥ 20 pack-year smoking history and 1 additional risk factor (other than secondhand smoke).[a]	2012
U.S. Preventive Services Task Force[8]	Age 55 to 80 years with ≥ 30 pack-year smoking history and smoking cessation < 15 years.	2013

[a]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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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

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 False positives ("false alarms")	380 356 (about 94%)
Invasive diagnostic procedures (among people with a false positive result) Major complications from invasive diagnostic procedures (e.g., infection, bleeding in lung, collapsed lung)	18 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/ya5jfvl
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/MedicareApprovedFacilitie/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 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]

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.

Calculate Pack-Years

(20 cigarettes = 1 pack)

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

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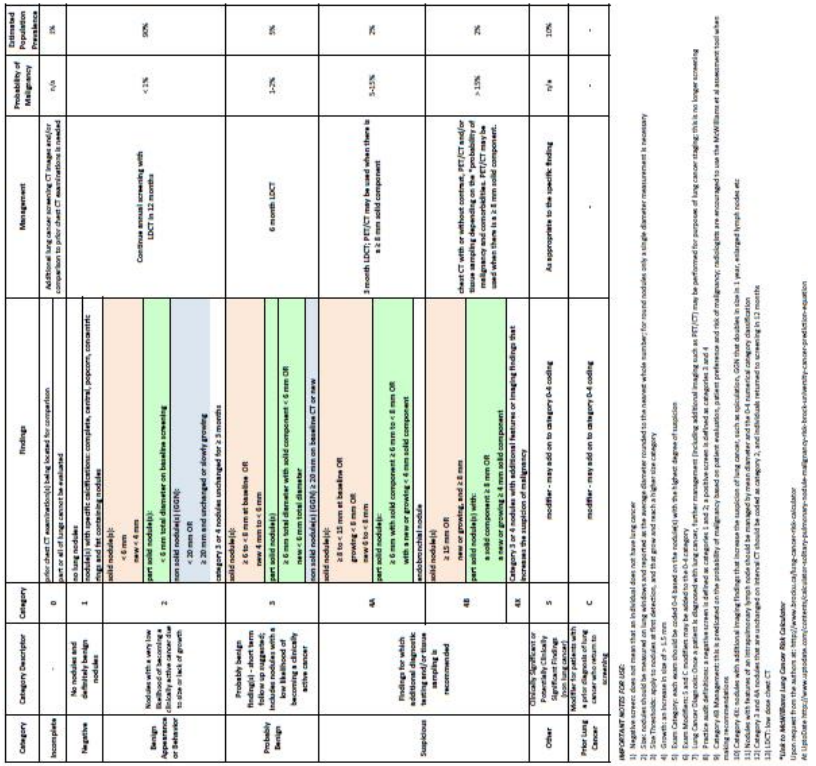
The Numbers Needed to Treat (NNT)
On Lung Cancer Screening

- The number needed to screen to prevent one death due to any cause is 219 (Bach et al., 2012).
- About 1 in 4 were harmed (false positive CT scan) (23.3% of the total number of CT scans across the 3 rounds) (Newman, 2011; The National Lung Screening Trial Research Team, 2011)
- About 1 in 30 were harmed (Had surgery as a follow-up diagnostic procedure, but were not found to have cancer) (Newman, 2011; Wender et al., 2013)
- 1 in 161 were harmed (surgical complication in those who were found not to have lung cancer) (0.06%) (Newman, 2011; The National Lung Screening Trial Research Team, 2011)

Lung-RADS™ Version 1.0 Assessment Categories Release date: April 28, 2014

Category Descriptor	Category Descriptor	Primary Category	Management
Incomplete	-	0	Additional lung cancer screening CT images and/or comparison to prior chest CT examinations is needed
Negative	No nodules and definitely benign nodules	1	Continue annual screening with LDCT in 12 months
Benign Appearance or Behavior	Nodules with a very low likelihood of becoming a clinically active cancer due to size or lack of growth	2	
Probably benign	Probably benign finding(s) - short term follow up suggested; includes nodules with a low likelihood of becoming a clinically active cancer	3	6 month LDCT
Suspicious	Findings for which additional diagnostic testing and/or tissue sampling is recommended	4A	3 month LDCT; PET/CT may be used when there is a ≥ 8 mm solid component
		4B	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 solid component.
Significant - other		S	
Prior Lung Cancer		C	



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, 76 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, 6 fewer people will die from any cause.

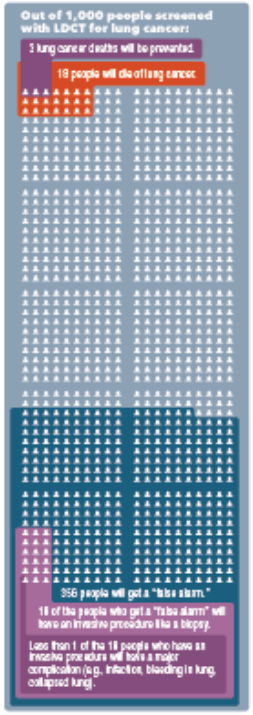
HARM: False alarms and unneeded additional testing

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.

AHRQ Agency for Healthcare Research and Quality

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: _____

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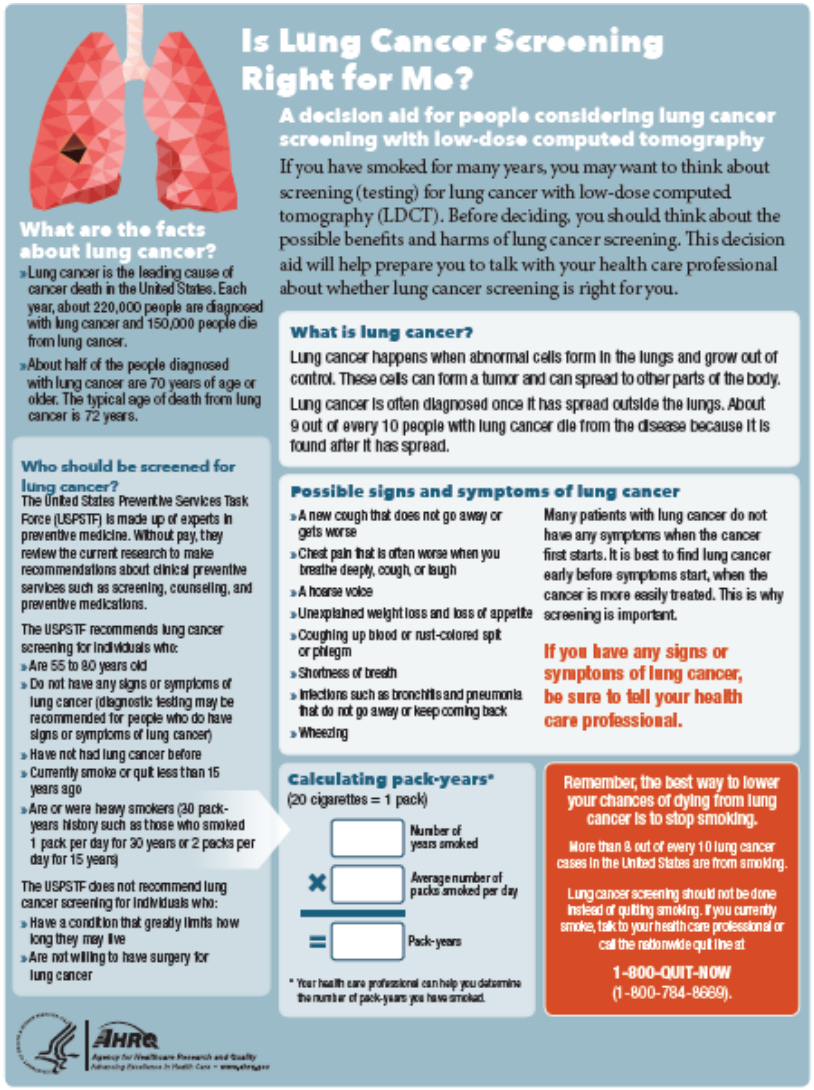
AHRQ Pub. No. 16-EHC007-13-A
March 2016



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.

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

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.

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

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)

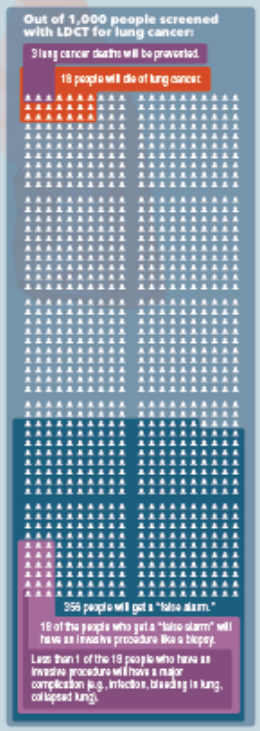
- If 1,000 people are not screened with LDCT for lung cancer, 75 will die from any cause.
- If 1,000 people are screened with LDCT once a year for 3 years, 70 will die from any cause.
- This means that with LDCT screening, 5 fewer people will die from all causes.

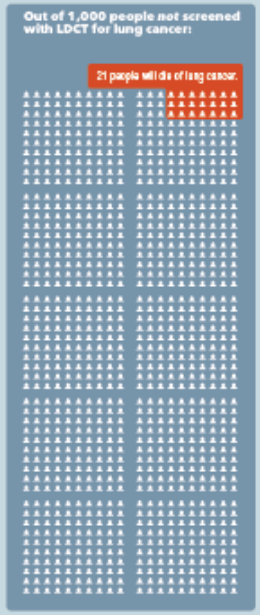
HARM: False alarms and unneeded additional testing

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.

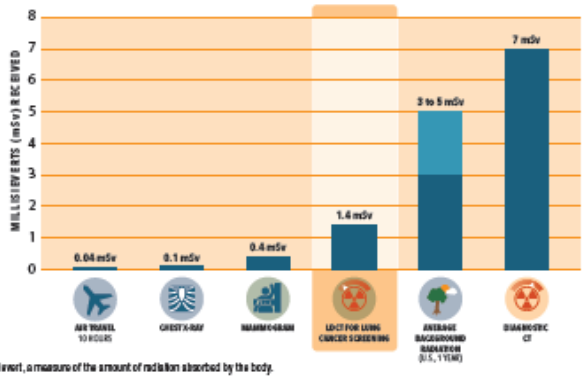
At the time of diagnosis, there is no way for health care professionals to know if the lung cancer will cause health problems over a lifetime. For this reason, almost all people who are diagnosed with lung cancer are treated.

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 OTHER QUESTIONS DO YOU HAVE?

_____

_____

_____

WHAT IS YOUR DECISION ABOUT LUNG CANCER SCREENING?

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

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 decision-making 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 follow-up 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.

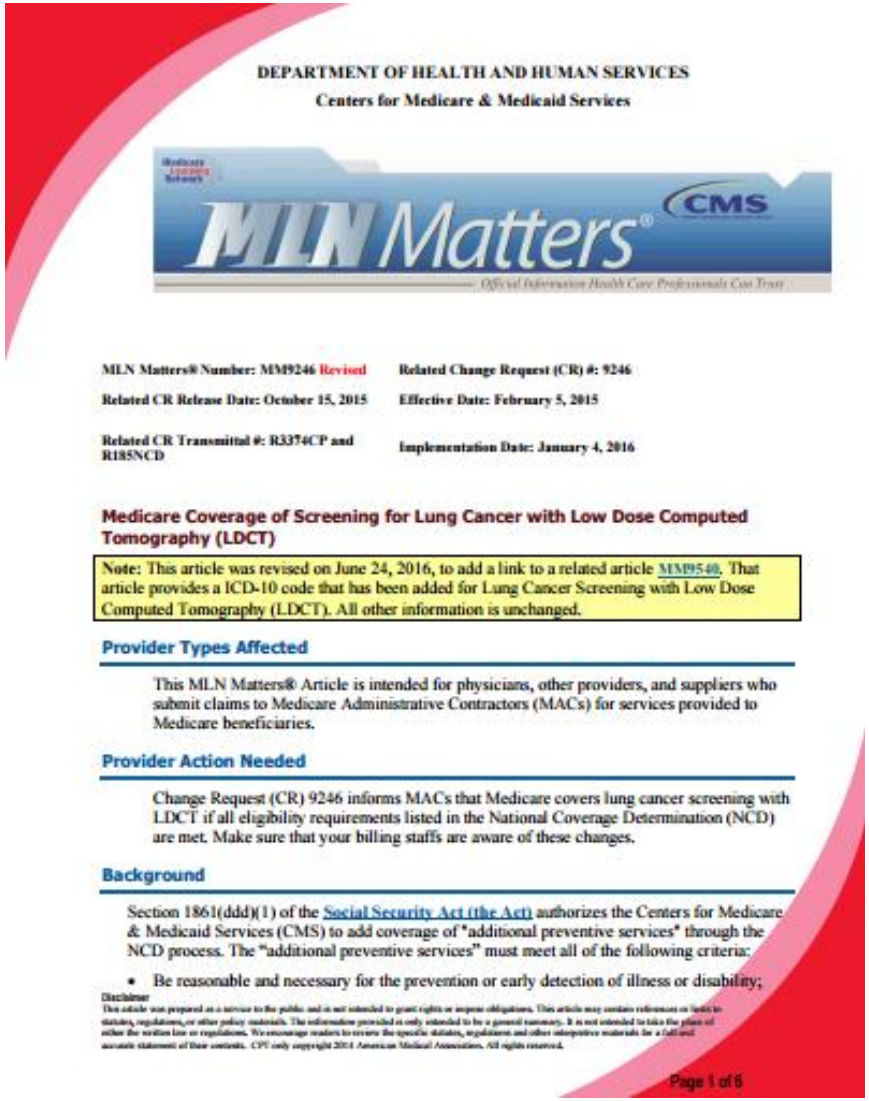
Ask your health care professional about the criteria if you have Medicare coverage.

There may be additional costs for follow-up 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.

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/MedicareApprovedFacilityItem/Lung-Cancer-Screening-Registries.html

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



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

MLN Matters®

MLN Matters® Number: MM9246 Revised | Related Change Request (CR) #: 9246

Related CR Release Date: October 15, 2015 | Effective Date: February 5, 2015

Related CR Transmittal #: R3374CP and R185NCD | Implementation Date: January 4, 2016

Medicare Coverage of Screening for Lung Cancer with Low Dose Computed Tomography (LDCT)

Note: This article was revised on June 24, 2016, to add a link to a related article MM9540. That article provides a ICD-10 code that has been added for Lung Cancer Screening with Low Dose Computed Tomography (LDCT). All other information is unchanged.

Provider Types Affected

This MLN Matters® Article is intended for physicians, other providers, and suppliers who submit claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

Provider Action Needed

Change Request (CR) 9246 informs MACs that Medicare covers lung cancer screening with LDCT if all eligibility requirements listed in the National Coverage Determination (NCD) are met. Make sure that your billing staffs are aware of these changes.

Background

Section 1861(ddd)(1) of the Social Security Act (the Act) authorizes the Centers for Medicare & Medicaid Services (CMS) to add coverage of "additional preventive services" through the NCD process. The "additional preventive services" must meet all of the following criteria:

- Be reasonable and necessary for the prevention or early detection of illness or disability;

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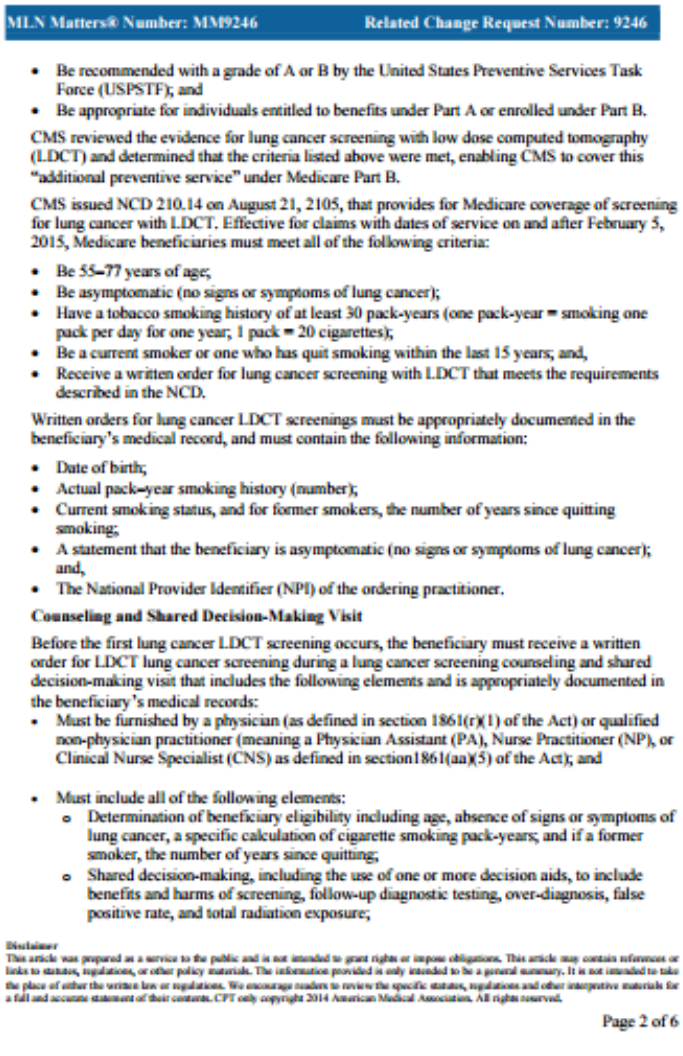

MLN Matters® Number: MM9246 Related Change Request Number: 9246

- Be recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF); and
- Be appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

CMS reviewed the evidence for lung cancer screening with low dose computed tomography (LDCT) and determined that the criteria listed above were met, enabling CMS to cover this "additional preventive service" under Medicare Part B.

CMS issued NCD 210.14 on August 21, 2105, that provides for Medicare coverage of screening for lung cancer with LDCT. Effective for claims with dates of service on and after February 5, 2015, Medicare beneficiaries must meet all of the following criteria:

- Be 55–77 years of age;
- Be asymptomatic (no signs or symptoms of lung cancer);
- Have a tobacco smoking history of at least 30 pack-years (one pack-year = smoking one pack per day for one year; 1 pack = 20 cigarettes);
- Be a current smoker or one who has quit smoking within the last 15 years; and,
- Receive a written order for lung cancer screening with LDCT that meets the requirements described in the NCD.

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

- Date of birth;
- Actual pack-year smoking history (number);
- Current smoking status, and for former smokers, the number of years since quitting smoking;
- A statement that the beneficiary is asymptomatic (no signs or symptoms of lung cancer); and,
- The National Provider Identifier (NPI) of the ordering practitioner.

Counseling and Shared Decision-Making Visit

Before the first lung cancer LDCT screening occurs, the beneficiary must receive a written order for LDCT lung cancer screening during a lung cancer screening counseling and shared decision-making visit that includes the following elements and is appropriately documented in the beneficiary's medical records:

- Must be furnished by a physician (as defined in section 1861(r)(1) of the Act) or qualified non-physician practitioner (meaning a Physician Assistant (PA), Nurse Practitioner (NP), or Clinical Nurse Specialist (CNS) as defined in section1861(aa)(5) of the Act); and

- Must include all of the following elements:
  - Determination of beneficiary eligibility including age, absence of signs or symptoms of lung cancer, a specific calculation of cigarette smoking pack-years; and if a former smoker, the number of years since quitting;
  - Shared decision-making, including the use of one or more decision aids, to include benefits and harms of screening, follow-up diagnostic testing, over-diagnosis, false positive rate, and total radiation exposure;

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- Counseling on the importance of adherence to annual lung cancer LDCT screening, impact of co-morbidities, and ability or willingness to undergo diagnosis and treatment;
- Counseling on the importance of maintaining cigarette smoking abstinence if former smoker; or the importance of smoking cessation if current smoker and, if appropriate, furnishing of information about tobacco cessation interventions; and,
- If appropriate, the furnishing of a written order for lung cancer screening with LDCT.

Written orders for subsequent annual LDCT screens may be furnished during any appropriate visit with a physician or qualified non-physician practitioner (PA, NP, or CNS)

There is also specific criteria that the reading radiologist and radiology imaging facility must meet. The radiology imaging facility must collect and submit data to a CMS-approved registry for each LDCT lung cancer screening performed. The data collected and submitted to a CMS-approved registry must include specific elements. Information regarding CMS-approved registries is posted at: http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/Lung-Cancer-Screening-Registries.html on the CMS website.

Coinsurance and Deductibles

Medicare coinsurance and Part B deductible are waived for this preventive service.

Health Care Common Procedure Coding System (HCPCS) Codes

Effective for claims with dates of service on and after February 5, 2015, the following HCPCS codes are used for lung cancer screening with LDCT:

- G0296 – Counseling visit to discuss need for lung cancer screening (LDCT) using low dose CT scan (service is for eligibility determination and shared decision making)
- G0297 – Low dose CT scan (LDCT) for lung cancer screening

In addition to the HCPCS code, these services must be billed with ICD-10 diagnosis code Z87.891 (personal history of tobacco use/personal history of nicotine dependence), ICD-9 diagnosis code V15.82.

NOTE: Contractors shall apply contractor-pricing to claims containing HCPCS G0296 and G0297 with dates of service February 5, 2015, through December 31, 2015.

Institutional Billing Requirements

Effective for claims with dates of service on and after February 5, 2015, providers may use the following Types of Bill (TOBs) when submitting claims for lung cancer screening, HCPCS codes G0296 and G0297: 12X, 13X, 22X, 23X, 71X (G0296 only), 77X (G0296 only), and 85X.

Medicare will pay for these services as follows:

- Outpatient hospital departments – TOBs 12X and 13X - based on Outpatient Prospective Payment System (OPPS);
- Skilled nursing facilities (SNFs) – TOBs 22X and 23X – based on the Medicare Physician Fee Schedule (MPFS);
- Critical Access Hospitals (CAHs) - TOB 85X – based on reasonable cost;

- CAH Method II – TOB 85X with revenue code 096X, 097X, or 098X based on the lesser of the actual charge or the MPFS (115% of the lesser of the fee schedule amount and submitted charge) for HCPCS G0296 only;
- Rural Health Clinics (RHCs) - TOB 71X - based on the all-inclusive rate for HCPCS G0296 only; and
- Federally Qualified Health Centers (FQHCs) – TOB 77X - based on the PPS rate for HCPCS G0296 only.

NOTE: For outpatient hospital settings, as in any other setting, services covered under this NCD must be ordered by a primary care provider within the context of a primary care setting and performed by an eligible Medicare provider for these services.

Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), Group Codes

MACs will use the following CARCs, RARCs, and Group Codes when denying payment for LDCT lung cancer screening, HCPCS G0296 and G0297:

Submitted on a TOB other than 12X, 13X, 22X, 23X, 71X, 77X, or 85X:

- CARC 170 - Payment is denied when performed/billed by this type of provider. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
- RARC N95 – This provider type/provider specialty may not bill this service.
- Group Code CO (Contractual Obligation) assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file).
  NOTE: For modifier GZ, MACs will use CARC 50.

For TOBs 71X and 77X when HCPCS G0296 is billed on the same date of service with another visit (this does not apply to initial preventive physical exams for 71X TOBs):

- CARC 97 - The benefit for this service is included in the payment/allowance for another service/procedure that has already been adjudicated. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
- RARC M15 - Separately billed services/tests have been bundled as they are considered components of the same procedure. Separate payment is not allowed.
  NOTE: 77X TOBs will be processed through the Integrated Outpatient Code Editor under the current process.
- Group Code CO assigning financial liability to the provider.

Where a previous HCPCS G0297 is paid in history in a 12-month period (at least 11 full months must elapse from the date of the last screening):

- CARC 119 – Benefit maximum for this time period or occurrence has been reached.
- RARC N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is

covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.
- Group Code CO assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file).
  NOTE: For modifier GZ, MACs will use CARC 50.

Because the beneficiary is not between the ages of 55 and 77 at the time the service was rendered (line-level):

- CARC 6: "The procedure/revenue code is inconsistent with the patient's age. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present."
- Group Code: CO (Contractual Obligation) assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file).
  NOTE: For modifier GZ, MACs will use CARC 50.

Because the claim line was not billed with ICD-10 diagnosis Z87.891:

- CARC 167 – This (these) diagnosis(es) is (are) not covered. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
- RARC N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.
- Group Code: CO assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file).
  NOTE: For modifier GZ, MACs will use CARC 50.

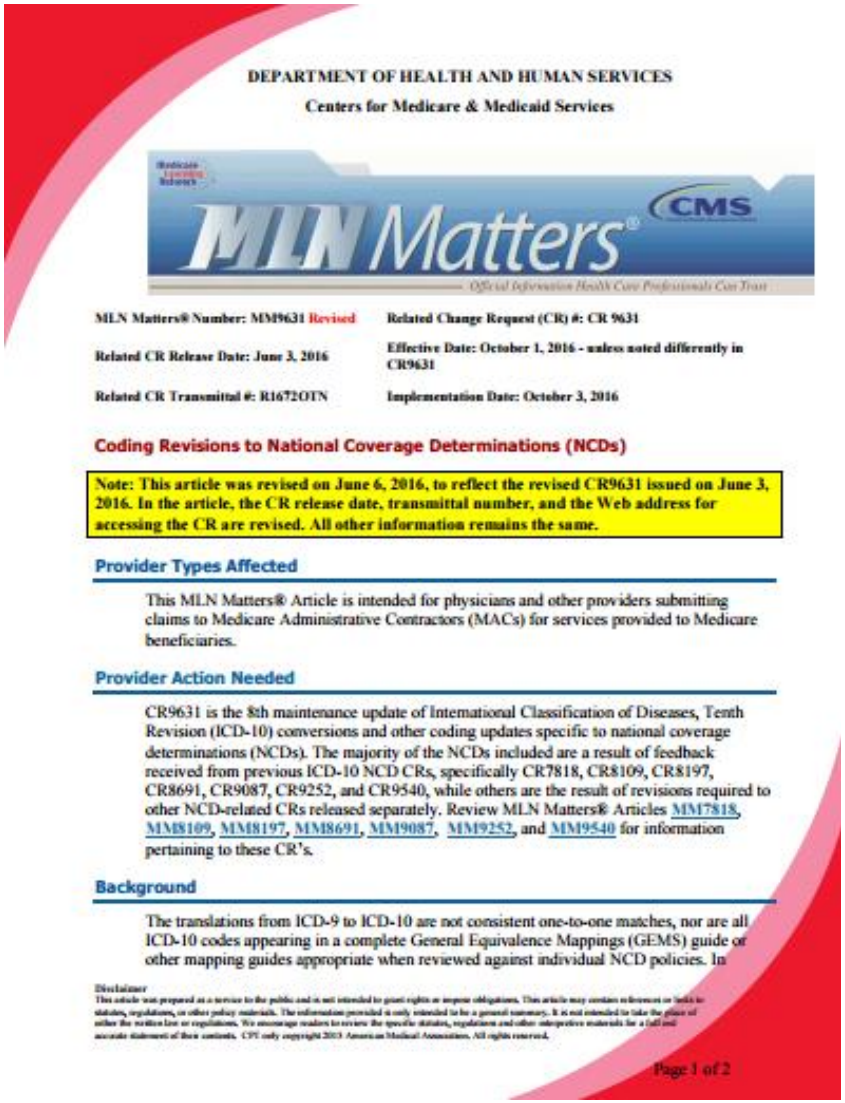
Additional Information

The official instruction, CR9246, consists of two transmittals:
1. Transmittal R3374CP, which updates the "Medicare Claims Processing Manual;" and
2. Transmittal R185NCD, which updates the "Medicare NCD Manual."

If you have any questions, please contact your MAC at their toll-free number. That number is available at: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html under - How Does It Work?

Document History

Date of Change	Description
June 24, 2016	The article was revised to add a link to a related article MM9540. That article provides a ICD-10 code that has been added for Lung Cancer Screening with Low Dose Computed Tomography (LDCT).
November 16, 2015	Initial article post



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

MLN Matters® CMS

Official Information Health Care Professionals Can Trust

MLN Matters® Number: MM9631 Revised | **Related Change Request (CR) #: CR 9631**

Related CR Release Date: June 3, 2016 | **Effective Date: October 1, 2016 - unless noted differently in CR9631**

Related CR Transmittal #: R1672OTN | **Implementation Date: October 3, 2016**

Coding Revisions to National Coverage Determinations (NCDs)

Note: This article was revised on June 6, 2016, to reflect the revised CR9631 issued on June 3, 2016. In the article, the CR release date, transmittal number, and the Web address for accessing the CR are revised. All other information remains the same.

Provider Types Affected

This MLN Matters® Article is intended for physicians and other providers submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

Provider Action Needed

CR9631 is the 8th maintenance update of International Classification of Diseases, Tenth Revision (ICD-10) conversions and other coding updates specific to national coverage determinations (NCDs). The majority of the NCDs included are a result of feedback received from previous ICD-10 NCD CRs, specifically CR7818, CR8109, CR8197, CR8691, CR9087, CR9252, and CR9540, while others are the result of revisions required to other NCD-related CRs released separately. Review MLN Matters® Articles MM7818, MM8109, MM8197, MM8691, MM9087, MM9252, and MM9540 for information pertaining to these CR's.

Background

The translations from ICD-9 to ICD-10 are not consistent one-to-one matches, nor are all ICD-10 codes appearing in a complete General Equivalence Mappings (GEMS) guide or other mapping guides appropriate when reviewed against individual NCD policies. In

addition, for those policies that expressly allow MAC discretion, there may be changes to those NCDs based on current review of those NCDs against ICD-10 coding. For these reasons, there may be certain ICD-9 codes that were once considered appropriate prior to ICD-10 implementation that are no longer considered acceptable.

No policy-related changes are included with these updates. Any policy-related changes to NCDs continue to be implemented via the current, long-standing NCD process. Updated NCD coding spreadsheets related to CR9631 are available at https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/CR9631.zip.

Edits to ICD-10 and other coding updates specific to NCDs will be included in subsequent, quarterly releases as needed. No policy-related changes are included with these updates. Any policy-related changes to NCDs continue to be implemented via the current, long-standing NCD process.

To be specific, CR9631 makes adjustments to the following NCDs:

- NCD 20.4 -Implantable Automatic Defibrillators
- NCD 20.7 -Percutaneous Transluminal Angioplasty (PTA)
- NCD 20.9 - Artificial Hearts
- NCD 20.29 - Hyperbaric Oxygen Therapy
- NCD 50.3 - Cochlear Implants
- NCD 110.18 - Aprepitant
- NCD 210.3 - Colorectal Cancer Screening
- NCD 220.4 - Mammography
- NCD 230.9 - Cryosurgery of Prostate
- NCD 260.9 - Heart Transplants
- NCD 210.4 - Smoking/Tobacco-Use Cessation Counseling
- NCD 210.4.1 - Counseling to Prevent Tobacco Use

Additional Information

The official instruction, CR 9631, issued to your MAC regarding this change is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1672OTN.pdf.

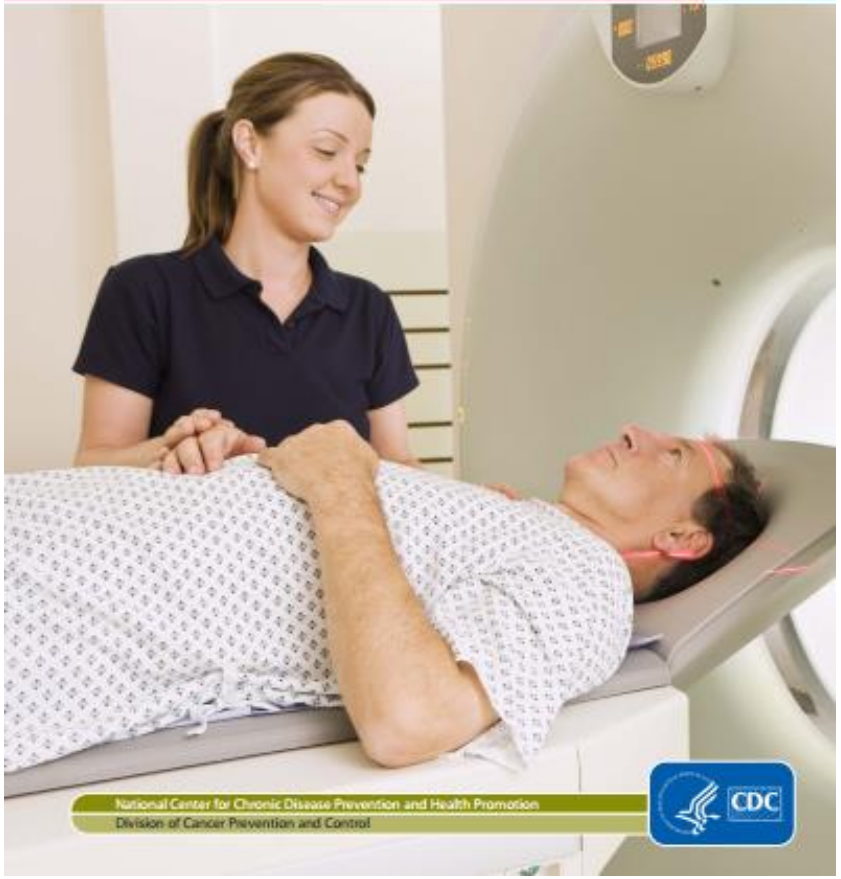
If you have any questions, please contact your MAC at their toll-free number. That number is available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html under - How Does It Work.

Document History

- June 6, 2016 - revised due to revised CR - no substantive change to the article.
- May 17, 2016 - initial issuance.

POLICIES & PRACTICES FOR CANCER PREVENTION

LUNG CANCER SCREENING PROGRAMS



POLICIES & PRACTICES FOR CANCER PREVENTION

CDC funds states, tribes, U.S. Affiliated Pacific Islands, and territories through the National Comprehensive Cancer Control Program (NCCCP) to form or support coalitions to fight cancer in their communities. The purpose of this report is to describe how NCCCP grantees can increase awareness about lung cancer screening programs, including cigarette smoking cessation, for persons at high risk for lung cancer. Examples of lung cancer screening-related activities conducted by some NCCCP grantees are also provided.

Lung cancer is the leading cause of cancer deaths among adults in the United States. In 2012, there were 210,828 cases of and 157,423 deaths from lung cancer.[1] Some groups have higher rates of new cases and death rates of lung cancer than others. The risk of lung cancer increases with age; therefore, older persons have higher rates than younger persons. Current cigarette smokers have higher rates of new lung cancer cases than persons who never smoked or who quit smoking.[2] Ten years after a person quits cigarette smoking, his or her risk for lung cancer drops by half.[3] If lung cancer is diagnosed before it has spread to other parts of the body, the 5-year survival rate is 55%.[4] Lung cancer is frequently diagnosed after it has spread, with survival rates ranging from 4.2% to 27.4%.[4] While lung cancer death rates have decreased over the past decade, many people continue to die from the disease.[1]

The goal of lung cancer screening is to enable detection of lung cancer before it has spread. Treatment can then be provided, which may reduce the likelihood of dying from lung cancer. However, lung cancer screening does not prevent the development of lung cancer. The best ways to reduce the risk of lung cancer are to not start smoking cigarettes, to quit if you smoke, and to avoid secondhand smoke.[5] Thus, lung cancer screening programs need to promote cessation of cigarette smoking among current smokers, and continued abstinence among former smokers.

CIGARETTE SMOKING CESSATION

What Resources are Available to NCCCP Grantees and Partners?

CDC has many resources to help people quit smoking (see www.cdc.gov/tobacco), including fact sheets, information about quitlines, free multimedia items that can be downloaded, and links to resources for state and community tobacco control programs. Tips from former smokers living with smoking-related diseases and conditions (Tips from Former Smokers campaign) are also available and may be accessed at www.cdc.gov/tobacco/campaign/tips/index.html. Resources for locating evidence-based strategies for reducing cigarette smoking and secondhand smoke exposure are found in Box 1.

BOX 1. RESOURCES FOR EVIDENCE-BASED COMMUNITY-BASED STRATEGIES FOR CIGARETTE SMOKING CESSATION

- Cessation Materials for State Tobacco Control Programs (www.cdc.gov/tobacco/quit_smoking/cessation/index.htm)
- Best Practices for Comprehensive Tobacco Control Programs, 2014 (www.cdc.gov/tobacco/stateandcommunity/best_practices/index.htm)
- The Community Guide to Reducing Tobacco Use and Secondhand Smoke Exposure (www.thecommunityguide.org/tobacco/index.html)

What Effective Cessation Treatments are Available?

Concerns about smoking-related health conditions, including lung cancer, could provide a powerful motivation for smokers to quit smoking. Because smoking is highly addictive, most smokers try to quit several times before succeeding, which means that health care providers often need to provide repeated help in this process. Smokers can improve their chances of quitting by using effective cessation treatments. These treatments include individual, group, and telephone counseling and seven FDA-approved cessation medications (including over-the-counter and prescription medications and nicotine and non-nicotine medications). As a result of the Affordable Care Act, coverage of cessation treatments is improving, but is still not comprehensive for all private insurance, Medicaid, and Medicare beneficiaries.[6] The CDC (www.cdc.gov/tobacco/quit_smoking/cessation/coverage/pdfs/coverage-508-1019.pdf) and the American Lung Association (http://www.lung.org/assets/documents/tobacco/helping-smokers-quit-2014.pdf) have summarized guidance from the U.S. Department of Health and Human Services on insurance coverage of tobacco cessation as a preventive service, including the types of health plans that are required to provide this coverage.

POLICIES & PRACTICES FOR CANCER PREVENTION

What Could Health Care Providers Do?

- Physicians and other health care providers play a critical role in motivating and helping smokers to quit. The 2008 Public Health Service Clinical Practice Guideline on Treating Tobacco Use and Dependence outlines a "5 A's" approach that clinicians should follow with patients who smoke, including (1) asking about tobacco use at every visit, (2) advising patients to quit, (3) assessing patients' willingness to make a quit attempt, (4) assisting patients in quit attempts, and (5) arranging follow-up.[7] Even brief advice to smokers improves quit rates, with more intensive advice and assistance having a progressively greater impact.
- In addition to providing direct counseling and assistance, health care providers and their teams could prescribe cessation medications for eligible smokers and refer them to other resources for more intensive help. One such resource is telephone quitlines, which have been shown to increase quit rates, to have broad reach, and to be effective with diverse populations.[7] Quitlines provide callers with counseling, practical assistance, and, in many cases, free nicotine replacement therapy.[8] Quitlines exist in all 50 states, the District of Columbia, Guam, and Puerto Rico; smokers can access their state quitline by calling 1-800-QUIT-NOW. In addition to telephone services, most U.S. quitlines offer web-based cessation services.[11,12] Quitlines referrals should be seen as a complement to, rather than a substitute for, direct cessation intervention performed by clinicians.

What Could NCCCP Grantees Do?

- NCCCP grantees could continue to collaborate with their tobacco control partners to implement evidence-based interventions for reducing cigarette smoking and secondhand smoke exposure identified in the Community Guide and in CDC's Best Practices for Tobacco Control Programs.
- Grantees could also work with comprehensive cancer control coalitions to increase awareness among health care providers about the importance of collecting information on current cigarette smoking status and smoking pack years in their medical record systems. This information could then be used to help health care providers identify and monitor persons who are at high risk for lung cancer, as well as to consistently advise patients to quit smoking and to offer them assistance in doing so. Clinical practice guidelines for treating tobacco use and dependence, including among older smokers, are available for health care providers (www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/clinicians/update/index.html).
- NCCCP grantees could explore partnerships with health care providers to develop stronger and more effective cigarette smoking cessation programs in the context of lung cancer screening. Referring smokers to quitlines is a strongly recommended strategy for providing tobacco cessation assistance. Quitlines can be authorized to follow up directly with a patient if the health care provider asks the patient to sign a release and then sends the release to the quitline.

Lung Cancer Screening

- Lung cancer screening needs to be thought of as a process, rather than a single test.
- The only recommended screening test for lung cancer is helical low-dose computed tomography (also called low-dose CT or LDCT) for persons who are at high risk for lung cancer because of their age and cigarette smoking history.
- The National Lung Screening Trial, a clinical research study in which participants at high risk for lung cancer were randomly assigned to receive lung cancer screening with LDCT or chest x-ray, found that screening with LDCT reduced lung cancer deaths.[9] In this test, an x-ray machine scans the body in a spiral path and uses low doses of radiation to make detailed pictures of the lungs.
- If an LDCT scan reveals a pulmonary nodule, additional evaluation may be needed to determine whether lung cancer is present.[10]
- The American College of Radiology has developed a Lung Imaging Reporting and Data System (Lung-RADS) to help classify nodules and standardize the interpretation of LDCT scans. A nodule may be monitored with serial CTs, evaluated further (for example with a PET scan or biopsy), or managed surgically depending on its size and chance of becoming cancer.[10]
- Clinical settings that have high rates of diagnostic accuracy using LDCT, appropriate follow-up protocols for positive results, and clear criteria for doing invasive procedures are more likely to duplicate the results found in carefully controlled research studies such as the National Lung Screening Trial.

Who Should Be Screened?

The U.S. Preventive Services Task Force (USPSTF) recommends (www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/lung-cancer-screening) annual lung cancer screening with LDCT for persons who—

- Have a history of heavy smoking (i.e., a smoking history of 30 pack years or more), *and*
- Smoke now or have quit within the past 15 years, *and*
- Are between 55 and 80 years old.

A pack year is defined as smoking an average of one pack of cigarettes per day for one year. A person can have a 30 pack-year history by smoking one pack a day for 30 years or two packs a day for 15 years.

A list of resources about lung cancer screening, including guidelines published by other organizations, is found in Box 2.

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What are Benefits of Screening?

A lung cancer screening test can:

- Detect cancer early: Lung cancer treatments are more effective, leading to improved survival, when cancer is detected at an early stage.
- Reduce deaths from lung cancer: Results from the National Lung Screening Trial showed that screening was associated with a 16% reduction in mortality from lung cancer among people with a history of heavy smoking.
- Increase opportunities for tobacco cessation: A quality lung cancer screening program should include a comprehensive tobacco cessation treatment program.

What are Risks of Screening?

A lung cancer screening test can lead to:

- False-positive test results: Screening could show that cancer is present when it is not, which may lead to anxiety and follow-up procedures that also have risks.
- False-negative test results: Screening could show that cancer is not present when it is, which may result in delays in seeking care.
- Overdiagnosis: Screening may lead to detection of lung cancer and unnecessary treatment in persons who would have died of other causes.
- Increased radiation exposure: There is a small chance that radiation from repeated LDCT tests can cause cancer in otherwise healthy people.
- False reassurance: A negative test result could lead to a smoker deciding to forego quitting cigarette smoking and to rely instead on ongoing screening as a risk reduction strategy.

What is the Status of Health Insurance Coverage for Screening?

The Centers for Medicare and Medicaid Services provides coverage for a lung cancer screening counseling and shared decision making visit, and if appropriate, annual screening for lung cancer with LDCT, as an additional preventive service benefit under the Medicare program, for persons who:

- Are Medicare (Part B) eligible;
- Are between 55-77 years old;
- Have a history of heavy smoking (at least 30 pack-years),
- Are a current smoker or stopped smoking within the past 15 years;
- Have no signs or symptoms of lung cancer (asymptomatic); and
- Receive a written order from their health care provider for LDCT lung cancer screening.

The lung cancer screening counseling and decision making visit includes counseling on the importance of maintaining cigarette smoking abstinence among former smokers and of smoking cessation among current smokers. If appropriate, information about tobacco cessation interventions is provided.

USPSTF uses four letter grades (A, B, C, D) and an I statement (insufficient evidence) to categorize recommendations based on the strength of the evidence and the balance of benefits and harms of a preventive service. The USPSTF's recommendation for screening persons at high risk for lung cancer with LDCT received a Grade B. The grade B for lung cancer screening means coverage is required with no cost-sharing in many private or employer-sponsored health insurance plans and by Medicaid in states that have accepted Medicaid expansion.[4]

BOX 2. RESOURCES FOR LUNG CANCER SCREENING

Recommendations and Guidelines

- U.S. Preventive Services Task Force (USPSTF) Lung Cancer Screening Recommendation (http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/lung-cancer-screening)
- Centers for Medicare and Medicaid Services Decision Memo for Screening for Lung Cancer with Low Dose Computed Tomography (LDCT) (CAG-00439N) (https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274)
- Comparison Chart of Lung Cancer Screening Guidelines and Recommendations (http://www.cdc.gov/cancer/lung/pdf/guidelines.pdf)

Information for Consumers

- Lung Cancer: What Screening Tests Are There? (CDC) (www.cdc.gov/cancer/lung/basic_info/screening.htm)
- Lung Cancer Screening (PDQ®) (NCI) (www.cancer.gov/types/lung/patient/lung-screening-pdq)
- Screening for Lung Cancer Consumer Fact Sheet (USPSTF) (http://www.uspreventiveservicestaskforce.org/Home/GetFileByID/1892)
- Screening for Lung Cancer (Veterans Affairs) (www.prevention.va.gov/docs/LungCancerScreeningHandout.pdf)
- National Comprehensive Cancer Network Guidelines for Patients. Lung Cancer Screening. Version 1.2015 (www.nccn.org/patients/guidelines/lung_screening/index.html)

Comprehensive Cancer Control
Collaborating to Conquer Cancer

How Could NCCCP Grantees Address Lung Cancer Screening?

Evidence-based strategies have not yet been identified for community implementation of lung cancer screening with LDCT. First, sufficient information about specific and appropriate strategies for community implementation of lung cancer screening must be developed for inclusion in The Community Guide. Until then, here are some potential activities that might be reasonable for NCCCP grantees and coalitions to consider.

Collect and Analyze Data

- Use cancer registry data to examine incidence and death rates for lung cancer and monitor changes in these indicators over time.
- Collaborate with state Behavioral Risk Factor Surveillance Survey (BRFSS) coordinators to add questions to enable calculation of smoking pack-years. Since current BRFSS surveys do not include questions to determine if a person has smoked 30 or more pack-years, this will help identify those who may be eligible for lung cancer screening. A potential source for question wording would be the 2015 National Health Interview Survey Cancer Control Supplement (http://www.cdc.gov/nchs/nhis/quest_data_related_1997_forward.htm), which includes questions to measure cigarette pack-years; to assess the prevalence of chest x-rays for lung cancer screening (chest x-rays are not recommended as a screening test so their use for screening would suggest the need for provider education); and to evaluate whether persons at high risk for lung cancer are being screened with LDCT. If resources permit, some states also should explore cognitive testing and validation of question wording. The results of cognitive testing for the 2015 NHIS Cancer Control Supplement Questions are available at: http://wwwn.cdc.gov/qbank/.
- Encourage electronic medical records systems to add information on pack years smoked. Information on cigarette pack years is necessary to identify persons eligible for screening.
- Analyze health care provider survey data on knowledge, attitudes, and practices about lung cancer screening and smoking cessation counseling among primary care providers.

Educate Existing Partners and Identify and Engage Potential Partners

- Educate cancer coalition members about lung cancer screening, cigarette smoking trends, and lung cancer rates (e.g., give presentations at conferences or provide webinars).
- Survey key partners to identify their needs and what resources they can add to your efforts.
- Identify potential partners (Box 3) at local, state and national levels and ask them to help you educate key stakeholders on strategies to implement high quality lung cancer screening for eligible groups.
- Work with radiation control departments to identify master lists of facilities that offer LDCT screening within the state, and to obtain technical information on the machines used and the amount of radiation exposure during LDCT imaging. State radiology departments already collect information on CT equipment, but existing lists may not allow easy identification of LDCT for lung cancer screening.
- Convene advisory panels that include experts from pulmonary medicine, thoracic radiology, thoracic surgery, radiation oncology, medical oncology, and primary care. These groups might advise on development of lung cancer screening operational policies that are evidence-based and help address questions that will occur as lung cancer screening is implemented in community practices.
- Collaborate with partners to promote smoking quitlines and develop or enhance lung cancer prevention and early detection efforts. For example, quitline providers could collaborate with their partners to develop educational materials for quitline staff about integrating assessment for lung cancer screening eligibility with tobacco cessation counseling.

Measure Your Effects

- Develop and implement an evaluation plan to measure the effect of programmatic efforts. Effective evaluation can also help track progress toward meeting cancer plan goals, can help set examples or guide other states, and may potentially inform development of Community Guide strategies for lung cancer screening implementation.
- The NCCCP Evaluation Toolkit provides guidance on how to plan and conduct evaluations. Evaluations need to be planned at the beginning of a program's lung cancer screening efforts. This ensures appropriate evaluation questions are developed, and data sources are in place to capture baseline information before intervention activities begin. Behavioral surveillance systems already in place (BRFSS, Library of Indicators and Data Sources [LIDS]) can be used to monitor changes in key indicators over time among adults.

The activities described above would help:

- Assess the community prevalence of lung cancer screening and patient-provider discussions about screening.
- Increase smoking cessation among current cigarette smokers who undergo screening.
- Inform plans to develop or enhance organized lung cancer screening programs in communities, continuing medical education opportunities for health care providers on lung cancer screening and tobacco cessation, and electronic medical record systems that track smoking history and lung cancer screening.
- Add evidence for appropriate and effective community implementation strategies for lung cancer screening programs.

BOX 3. POTENTIAL PARTNERS TO ENGAGE IN LUNG CANCER SCREENING PROGRAM EFFORTS

Consider working with:

- Health care providers, clinics, and medical associations to increase lung cancer screening and cigarette smoking cessation among persons at high risk for lung cancer.
- State and local health departments, who can provide crucial support by identifying, tracking, and providing data (outcome measures) and mapping community problems. They can also provide forums for community planning and conduct and sponsor education of community leaders.
- State and local tobacco control programs to provide unified messages about the importance of tobacco control to prevent lung cancer and lung cancer screening to reduce lung cancer deaths.

Other organizations to consider include:

- Professional and non-profit organizations
  - American Cancer Society
  - American College of Radiology (local chapter)
  - American Lung Association
  - Lung Cancer Alliance
  - National Association of Chronic Disease Directors
  - National Behavioral Health Network for Tobacco and Cancer Control
  - National Comprehensive Cancer Control Network
  - Tobacco control programs, radiation control departments, professional medical organizations (pulmonary medicine, thoracic radiology and surgery, radiation therapy, medical oncology, and lung pathology), health care systems or other health care providers with electronic medical record systems, and environmental health agencies to promote smoking quitlines and develop or enhance lung cancer prevention and early detection efforts.
- Federal and international agencies and organizations
  - National Cancer Institute
  - Centers for Disease Control and Prevention: Tips Campaign
  - Substance Abuse & Mental Health Services Administration
  - World Health Organization

How Have Selected NCCCP Grantees Addressed Lung Cancer Screening?

- Delaware launched an initiative using small and large media to educate health care providers and current and former smokers about lung cancer screening services offered to eligible adults by the state's Screening for Life Program. Providers also received a tool kit, which includes a waiting room poster, a script pad with the direct line of a lung cancer screening nurse navigator, a screening authorization form, and a referral form to Delaware's quitline.
- Kansas added questions to the state's 2012-13 Adult Tobacco Survey (ATS) and 2015 BRFSS to collect baseline data on the prevalence of health care provider discussions about lung cancer screening with patients at high risk for lung cancer. The survey data will be used to identify priorities and inform strategies to increase lung cancer screening across the state. Findings from the ATS were presented at CDC's 2014 cancer grantee meeting, as well as the 2015 annual meeting of the Council of State and Territorial Epidemiologists.
- Kentucky formed a Lung Cancer Screening and Early Detection Network that has more than 38 organizations working together toward lung cancer screening, tobacco cessation treatment, secondhand smoke and radon prevention. Several of these partner organizations are working on research projects designed to: (1) expand awareness of lung cancer screening in communities, (2) promote shared decision making among screening candidates, (3) train primary care providers about appropriate referral patterns for lung cancer screening, and (4) facilitate implementation of high quality lung cancer screening among programs across the state.
- South Carolina collaborated with partners on a dissemination project to advance lung cancer screening across the state. The project included development and dissemination of a shared decision-making aid to assist health care providers in their discussions about lung cancer screening with patients at high risk for lung cancer, as well as a lung cancer screening fact sheet for decision makers and stakeholders. In collaboration with the South Carolina American Academy of Family Physicians, a quantitative survey of primary care providers was conducted to assess their knowledge, attitudes, and practices regarding lung cancer screening with LDCT.
- Vermont partnered with the American Lung Association and University of Vermont College of Medicine staff and students to conduct a survey and focus group to assess awareness of lung cancer screening and barriers to screening among residents at high risk for lung cancer. They also worked with the American Lung Association to develop training on lung cancer screening for primary care providers, and assisted the Medicaid Clinical Utilization Board in estimating the number of Medicaid recipients that meet the U.S. Preventive Services Task Force criteria for lung cancer screening eligibility.

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More Information

Division of Cancer Prevention and Control
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention

4770 Buford Hwy NE, Mailstop F-76, Atlanta GA 30341-3717
800-CDC-INFO (800-232-4636) • TTY: (888) 232-6348
www.cdc.gov/cancer/promoting_prevention.htm • Twitter: @CDC_Cancer

effective for urticaria. Medications that modulate neurologic function, including gabapentin, are effective for recalcitrant pruritus and less sedating than oral antihistamines.[2] Treatment of comorbid depression or anxiety can also improve the symptoms and burden of pruritus.

Patients without a dermatologic, neurologic, or psychiatric cause for pruritus should be asked about the presence of fevers, chills, night sweats, and/or unintended weight loss, as well as undergoing a full review of systems to assess for localizing symptoms. Physical examination would include palpation of the lymph nodes, spleen, and liver. Testing for a metabolic or neoplastic source of pruritus should be considered for patients with chronic, generalized pruritus who lack a primary skin disease.[3] Systemic evaluation of these patients can include malignant neoplasm and thyroid, renal, hepatic, and infectious diseases.[4] Thus, it is important to remember the association of chronic pruritus and internal systemic diseases but to limit screening to the patients without recognizable skin disease.

Published Online: April 25, 2016. doi:10.1001/jamainternmed.2016.1041.

Conflict of Interest Disclosures: None reported.

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TEACHABLE MOMENT

LESS IS MORE

Competing Mortality in Cancer Screening
A Teachable Moment

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Story From the Front Lines

A 70-year-old man saw his primary care clinician and expressed concern about his lung cancer risk after learning a friend had recently died of it. The patient had had an 80-pack-year history, and had quit 7 years previously. His physician ordered a screening chest computed tomographic (CT) scan, which demonstrated a spiculated 13-mm lung nodule that was new when compared with scans done previously for other reasons. This prompted a positron emission tomographic scan, which showed metabolic activity, raising the suspicion for lung cancer. He was referred to a pulmonary-nodule clinic.

The man presented to the pulmonary clinic in a wheel chair while receiving continuous oxygen. His medical history revealed severe diastolic heart failure; chronic obstructive pulmonary disease; obesity (his body mass index, calculated as weight in kilograms divided by height in meters squared, was 54); diabetes mellitus with microvascular complications, including stage III chronic kidney disease; and peripheral neuropathy. Additional medical history included several recent falls attributed to progressive neuropathy and deconditioning. These considerations were discussed with the patient and ultimately, invasive diagnostic testing was discouraged. A conservative plan that included a repeated CT scan in 4 months was mutually agreed on. Two months after this visit, the patient was admitted and treated for pneumonia. While recovering in the hospital, his primary team noted that this nodule had not undergone workup and he had another CT scan, which demonstrated interval growth. He was scheduled for an outpatient CT-guided biopsy.

Prior to the biopsy, the patient was rehospitalized for pneumonia, this time requiring intensive care unit admission. His medical history was addressed at a multidisciplinary thoracic tumor conference. He was not a surgical candidate, and attempts to biopsy the nodule were also considered to be high risk. Therefore, he was referred to radiation oncology to discuss the risks and benefits of empirical radiation therapy without a tissue diagnosis. Prior to meeting with radiation oncology, in follow-up at an outpatient clinic 2 weeks after discharge, he had increasing dyspnea, was delirious, and was thought to yet again have pneumonia. He was ultimately referred to palliative care for consideration of hospice.

Teachable Moment

Common cautions in the context of screening for lung cancer include high false-positive rates, complications of invasive procedures, radiation exposure, and psychological stress. Other considerations, which this patient's case illustrates, are the importance of considering competing mortality when assessing the potential benefits of screening and overdiagnosis. The US Preventive Services Task Force clearly emphasizes this in their recently released guideline statement: "Screening may not be appropriate for patients with ... comorbid conditions, particularly those who are in the upper end of the screening age range."[1,2] In other words, screening should be restricted to those whose health permits them to benefit from and tolerate the additional testing and treatment required.

This is also reflected in the "shared decision making" requirement of the Centers for Medicare and

Medicaid Services decision[3] to cover lung cancer screening for high-risk Medicare beneficiaries. This emphasizes the idea of targeting screening based on patient comorbidities and individualized preferences. Physicians should resist the temptation and not feel obliged to offer screening to patients only because they meet age and smoking requirements. Rather, as this case illustrates, physicians will be doing a disservice to patients and the health care system if they offer screening to patients that will not benefit.

As screening for lung cancer is implemented in a wider population, we can expect screening subjects who are sicker than the National Lung Cancer Screening Trial participants and arguably sicker than the populations offered other cancer screening interventions owing to targeting patients with considerable smoking history. We can also expect a reduction in overall benefit as follow-up compliance inevitably regresses away from the 95% adherence attained in a clinical trial. This stresses the importance of careful selection of patients who are likely to benefit from intervention.

Overdiagnosis is related to competing mortality, in that it represents the detection of clinically insignificant cancers. This determination varies from patient to patient because those with lower life expectancy have a greater chance of experiencing "overdiagnosis" during cancer screening. Both retrospective studies[4,5] of actual practice patterns and survey data confirm that screening for cancer is offered to patients with limited life expectancy and therefore limited potential to benefit from screening. Recognizing the impact of comorbid illness on the effectiveness of cancer screening is arguably more important in the patient population eligible for lung cancer screening owing to a high prevalence of smoking-related comorbidities.

As lung cancer screening is more widely adopted, considerations of comorbid disease must be incorporated into shared decision-making, and decision aids that facilitate this might prove very useful. In our patient, it was hard to predict his accelerated decline but comparatively very easy to predict that, if a screen-detected cancer was present, he would die with it, not as a result of it.

Published Online: April 4, 2016. doi:10.1001/jamainternmed.2016.1210.

Conflict of Interest Disclosures: None reported.

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Five As of Smoking Cessation

ASK about tobacco use during every visit

ADVISE all smokers to quit at every visit

ASSESS the patient's willingness to quit at every visit

ASSIST the patient in his/her attempt to quit within 2 weeks with pharmacotherapy or counseling

ARRANGE follow-up contact within 1st week after quitting

5 R's to Treat Tobacco Use

RELEVANCE – educate why quitting is relevant to the patient

RISKS – Identify negative consequences of tobacco use

REWARDS – Identify potential benefits to smoking cessation

ROADBLOCKS – Identify barriers to quitting

REPETITION – Repeat motivational intervention at each visit

(USPSTF, n.d.)

Stages of Change

1. Pre-contemplation: Not ready for change
2. Contemplation: Thinking about change
3. Preparation: Getting ready to make a change
4. Action: Making the change
5. Maintenance: Sustain the behavior change into lifestyle

Smoking Cessation Treatment Options

Behavioral Counseling

- Smoking cessation program
- Free telephone quit line (1-800-QUIT-NOW)
- Computer programs
- Text messaging
- Web-based interventions
- Phone apps

Pharmacotherapy:

Nicotine Replacement Therapies	About	Dosing	Side Effects/ Precautions
• Transdermal patch	Superior to placebo in RCTs, increasing quit rate 2-fold Use of long-acting and short-acting recommended – combination more effective than either alone in a meta-analysis	10+ cigarettes per day: 21mg/day patch x 6 weeks fb 14mg/day x 2 weeks, f/b 7mg/day x 2 weeks For those who smoke 10 or less cigarettes/day or weigh less than 45kg: 14mg/day x 6 weeks f/b 7mg/day x 2 weeks	Insomnia, vivid dreams with overnight use
Adjunctive Short-Acting Agents			
o Gum	Peak blood nicotine level 20 minutes after chewing Chew and park method recommended	25+cigarettes/day: 4mg dose q1-2hrs 2mg dose for lighter smokers	May exacerbate TMJ disease, or damage dental appliances
o Lozenge	Similar pharmacokinetic profile to gum	Smokers who smoke within 30 min of awakening: 4mg dose q1-2hrs 2mg dose for all other smokers	Abdominal pain, diarrhea, headache, mouth irritation/ulcers, N/V, palpitations
		Maximum daily dose: 5 lozenges q 6hrs or 20 lozenges/day	
o Inhaler	Similar pharmacokinetics to gum Addresses behavioral aspect of smoking	6-16 cartridges/day x 6-12 wks, then gradual reduction over 6-12 wks	Mouth/throat irritation, may cause bronchospasm
o Nasal spray	Peak nicotine after 10 minutes (faster than other methods)	1-2 sprays/hour x 3 months Maximum dose 10 sprays/hour or 80 sprays/day	Nasal/throat irritation, rhinitis, sneezing, tearing
Varenicline	Binds to and creates partial stimulation of alpha-4 beta-2 nicotinic receptor → decreases symptoms of nicotine withdrawal Blocks nicotine in tobacco smoking from binding to the receptor → decreases rewarding aspect of smoking Higher rates of tobacco abstinence at 3 and 6 months compared to nicotine patch, bupropion, and placebo	Quit smoking 1 week after starting varenicline 0.5mg daily x 3 days, 0.5mg BID x 4 days, 1mg BID for remainder of 12 weeks	Stop medications with agitation, behavior changes, depressed mood, hostility, suicidal attempts, and suicidal ideation May increase risk of CV events in pts with known CVD Abnormal dreams, impaired ability to operate or drive heavy machinery, nausea, insomnia, moderate to severe skin reactions, nausea, syncope,

			visual disturbances
Bupropion	Enhance CNS noradrenergic and dopaminergic release More effective than placebo, efficacy in specific populations – smokers who are African-American or who have stable CVD or COPD	Start one week before quitting 150mg/day x 3 days, 150mg BID thereafter for at least 12 weeks	Associated with increased risk of suicidal/self-injurious behavior or depression Monitor for agitation, behavior changes, depressed mood, suicidal attempts, and suicidal ideation Contraindicated with seizure disorder Agitation, dry mouth, headache, insomnia
Other • Nortriptyline • Cytosine • Clonidine • SSRIs/anxiolytics • Nicotine vaccine • Electronic cigarette			

Alternative Therapies

- Acupuncture
- Hypnosis
- Financial incentives

(Rigotti, 2016a; Rigotti, 2016b)

Lung Cancer Screening Resource Websites

Organization/Title	Website
American Cancer Society	www.cancer.org
AHRQ – Agency for Healthcare Research and Quality	www.ahrq.gov
American College of Radiology (ACR) – Lung Cancer Screening FAQs	http://www.acr.org/Advocacy/eNews/20150612-Issue/20150612-ACR-Posts-Lung-Cancer-Screening-FAQs
ACR – Lung Cancer Screening Resources	www.acr.org/Quality-Safety/Resources/Lung-Imaging-Resources
ACR – Lung RADS	http://www.acr.org/Quality-Safety/Resources/LungRADS
American Lung Association	www.lung.org
Centers for Disease Control and Prevention	www.cdc.org
Lung Cancer Alliance – For Screening Professionals	http://www.lungcanceralliance.org/am-i-at-risk/screening-center-resources/
Lung Cancer Screening (PDQ) – Health Professional Version	www.cancer.gov/types/lung/hp/lung-screening
Lung Cancer Screening PDQ – Patient Summary	www.cancer.gov/types/lung/patient/lung-screening-pdq
Society of Thoracic Radiology	www.thoracicrad.org
U.S. Preventive Services Task Force	www.uspreventiveservicestaskforce.org

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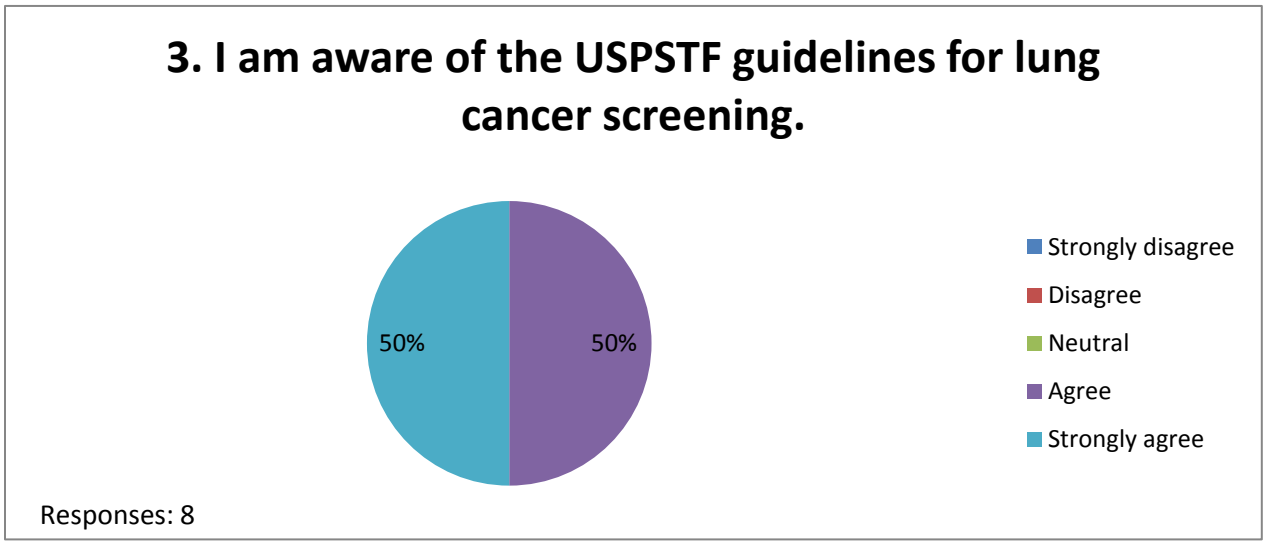
Appendix D

Pre-Implementation Survey Results

1. How many referrals for lung cancer screening have you made over the past week?
    a. 0
    b. 0
    c. 0
    d. 0
    e. 0
    f. 0
    g. 0
    h. 0
2. How many referrals for lung cancer screening have you made over the past month?
    a. 1
    b. 0
    c. 0
    d. 0
    e. 0
    f. 0
    g. 2
    h. 0



4. I am aware of the Centers for Medicare and Medicaid Services (CMS) requirements for a shared decision-making visit for lung cancer screening.

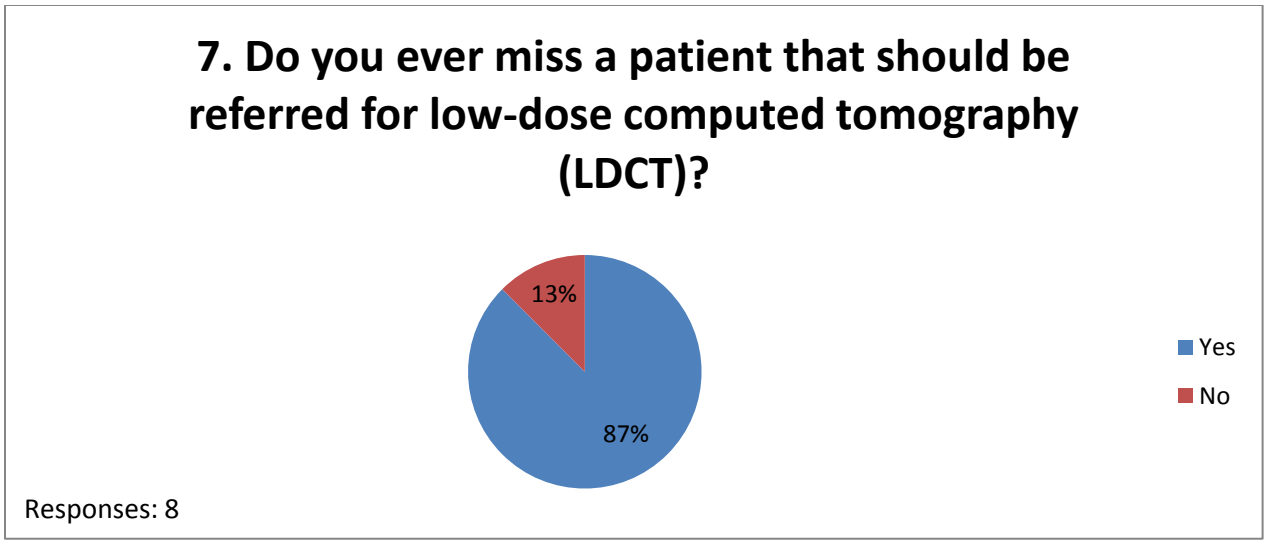
Responses: 8

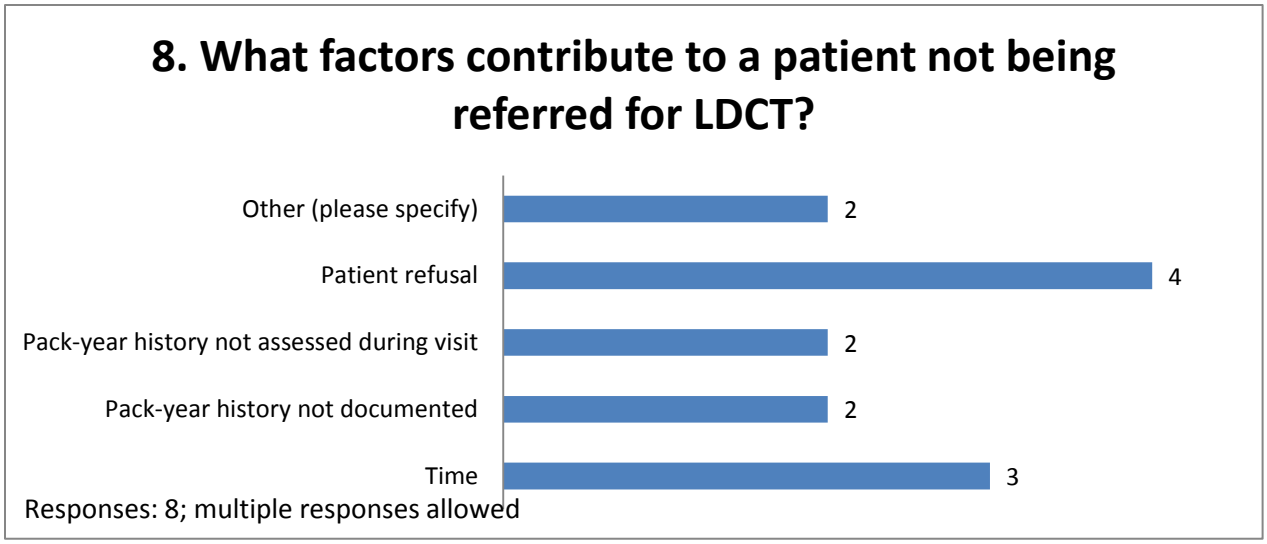
5. I address all of the required aspects for a shared decision-making visit for Medicare patients.

Responses: 8

6. I find it easy to have discussions with patients about lung cancer screening.

Responses: 8





Other:

- Noncompliant patient population with many unaddressed needs of much higher acuity. Epic also not capable of adequate clical care reminders not limiteed to Lung CA screening (ie say patient is a candidate despite adequate documentation by quit date that they aren't. A generally very poor clinical version of Epic waste time of clinicians making it harder to provide appropriate care.
- dont have time to address screening guidelines at every visit

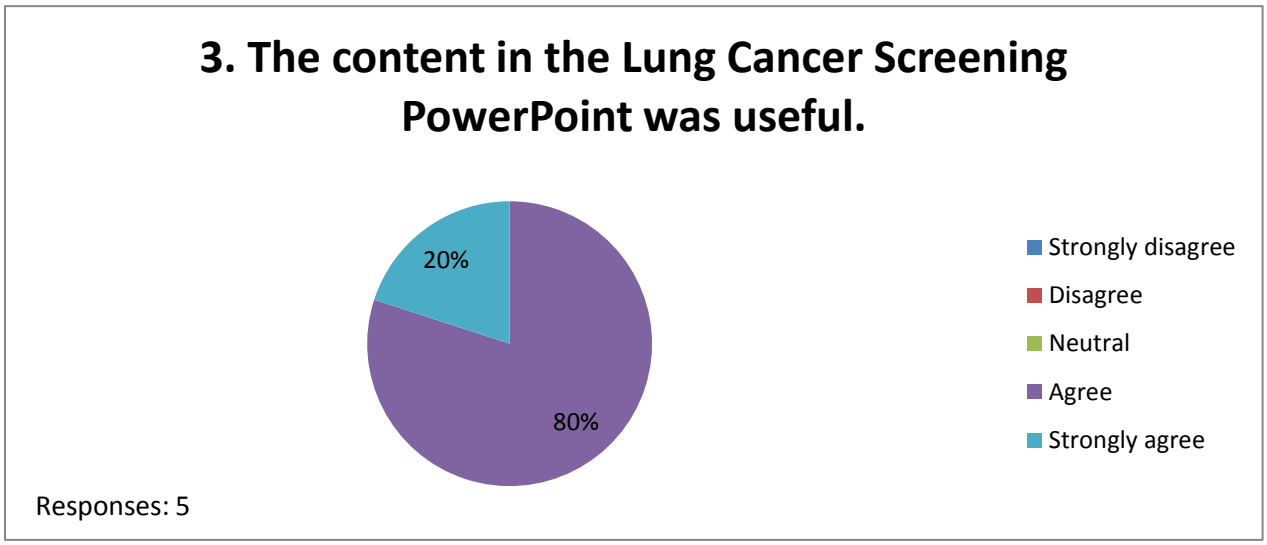
9. What kind of resources do you have and use for lung cancer screening?
    a. Smoking hx
    b. Up to date, Dynamed, PCOI
    c. Internet
    d. Very little
    e. I google different resources each time.
    f. None that im aware of
    g. Dot phrases and handouts

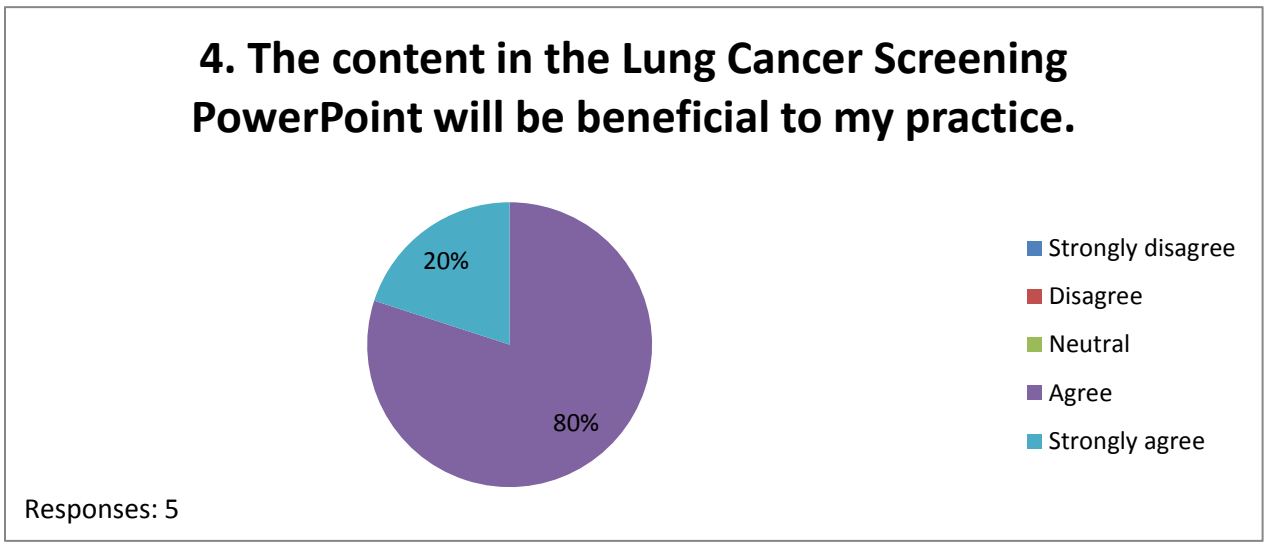
    h. None
10. What kind of resources would be helpful?
    a. If a pos smoking hx, follow up questions that then if certain number pos direct me to ordering test
    b. Lung Cancer Association algorithm
    c. Printed guidelines or website that would be easy to get to.
    d. Actual insurance coverage for this for each patient that is a candidate. More proactive approach by our pulmonologist to address this as PCPs are dumped on extensively w/I NWH.
    e. A pro and con tip sheet for the patient.
    f. handouts
    g. same as above
    h. A smart phrase with all talking points
11. What education would be helpful regarding lung cancer and screening?
    a. Patient handout
    b. Videos, presentation
    c. A review of the guidelines.
    d. see other
    e. Anything
    f. medicare guidelines education
    g. percentages of diagnosed lung cancer from this screening
    h. Tool on epic
12. What barriers are there to educating your patients regarding lung cancer screening?
    a. Awareness
    b. Handouts, videos
    c. Time and easily accessible and easily understood education materials.
    d. se other
    e. Visit time.
    f. understanding the work up afterwards should they get a positive screen
    g. time
    h. none
13. What barriers are there to referring patients for screening?
    a. Often missed bc not there to discuss smoking
    b. Insurance coverage
    c. Not sure there are any.
    d. lack of adequate clinical support, inappropriate and poorly function Epic version adopted by Partners. Dumping by specialist. Lack of information about each individuals insurance coverage for this. General disregard of PCP's time by administration and many specialist.
    e. Not having all the info needed for ordering the CT.
    f. healthcare literacy
    g. patient acceptance
    h. Pts usually are not interested
14. Please provide any additional comments.
    a. N/A
    b. No

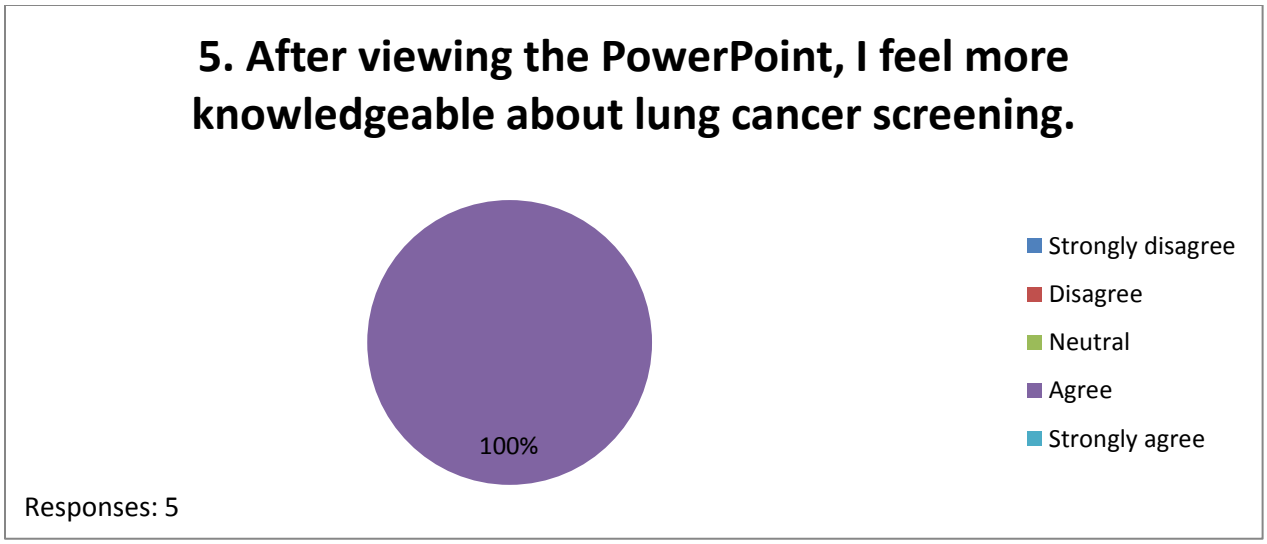
c. I'm worried about the high false positive rate

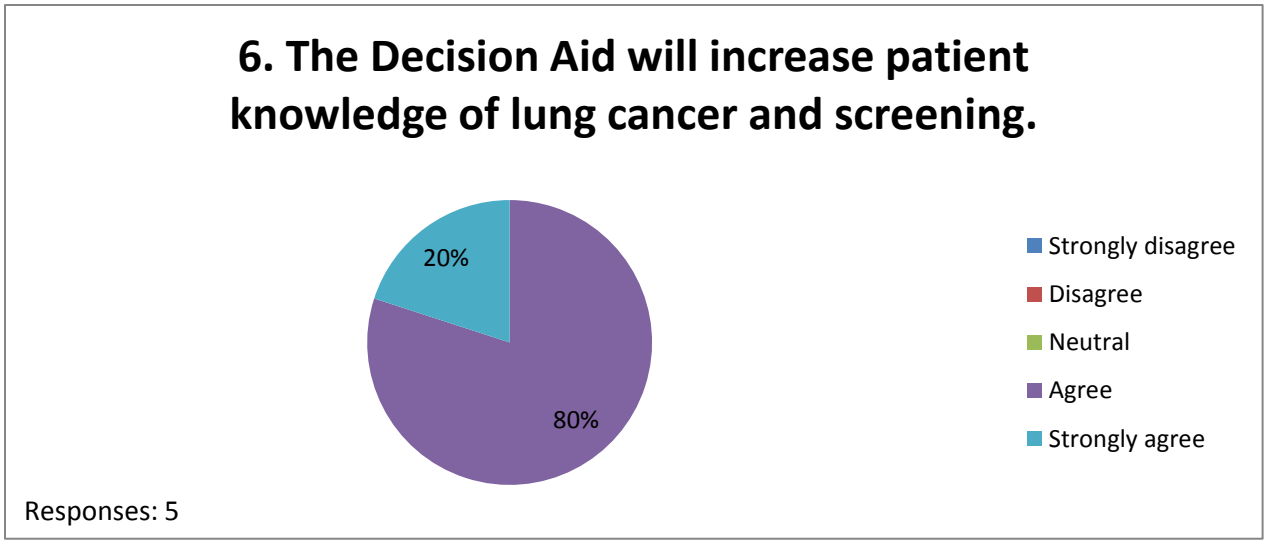
Immediate Post-Educational Intervention Survey

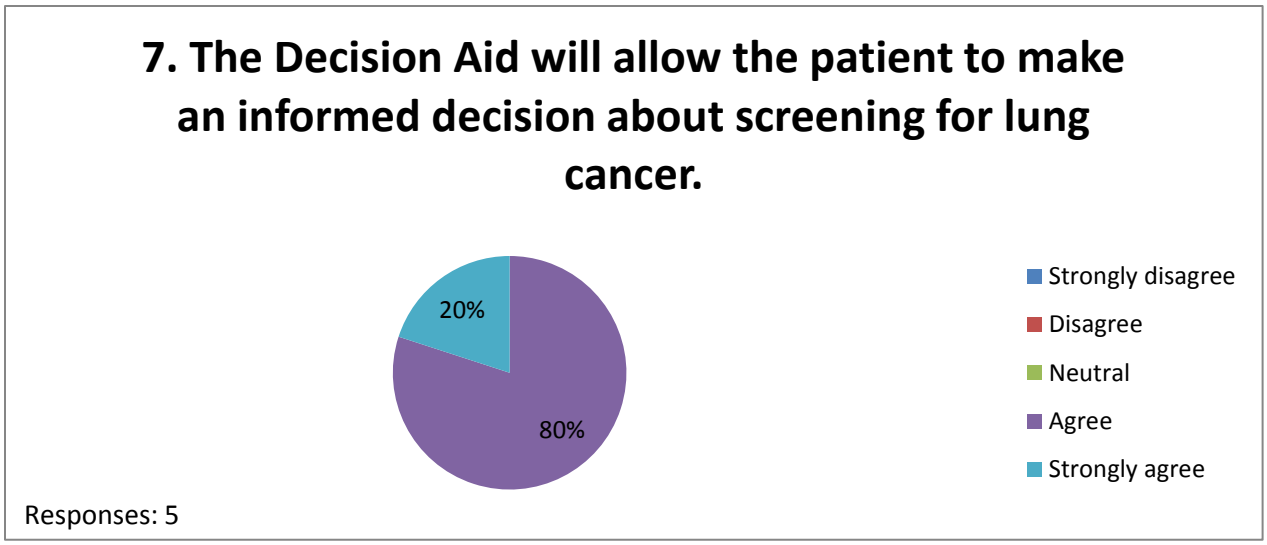
1. How many referrals for lung cancer screening have you made over the past week?
   a. None
   b. 0
   c. 0
   d. 0
   e. 1
2. How many referrals for lung cancer screening have you made over the past month?
   a. None
   b. 1-2
   c. 0
   d. 0
   e. 1

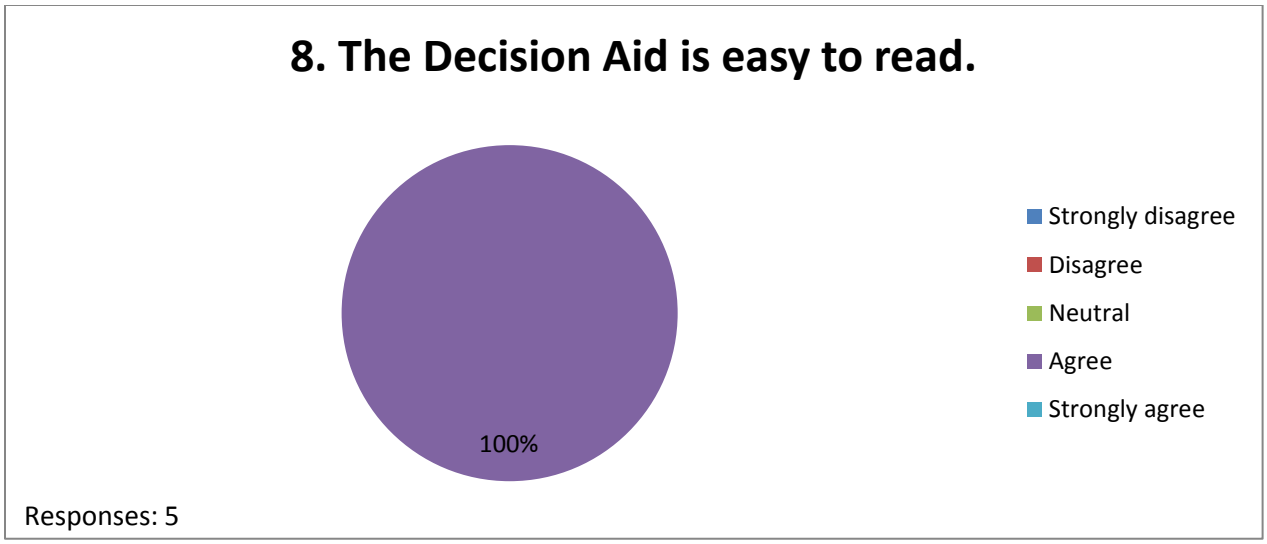


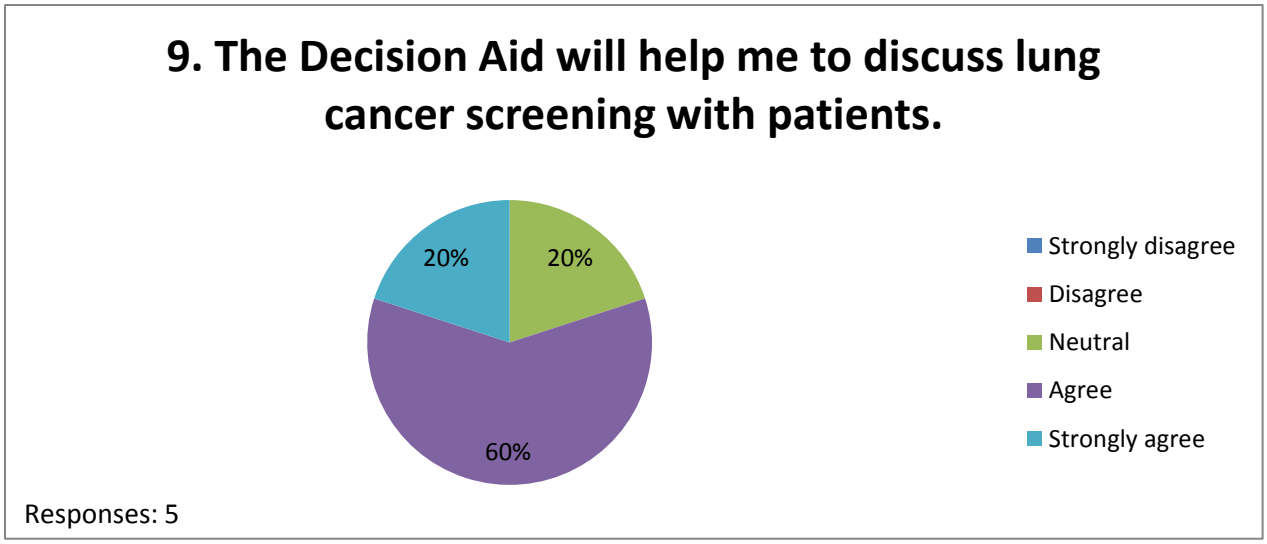


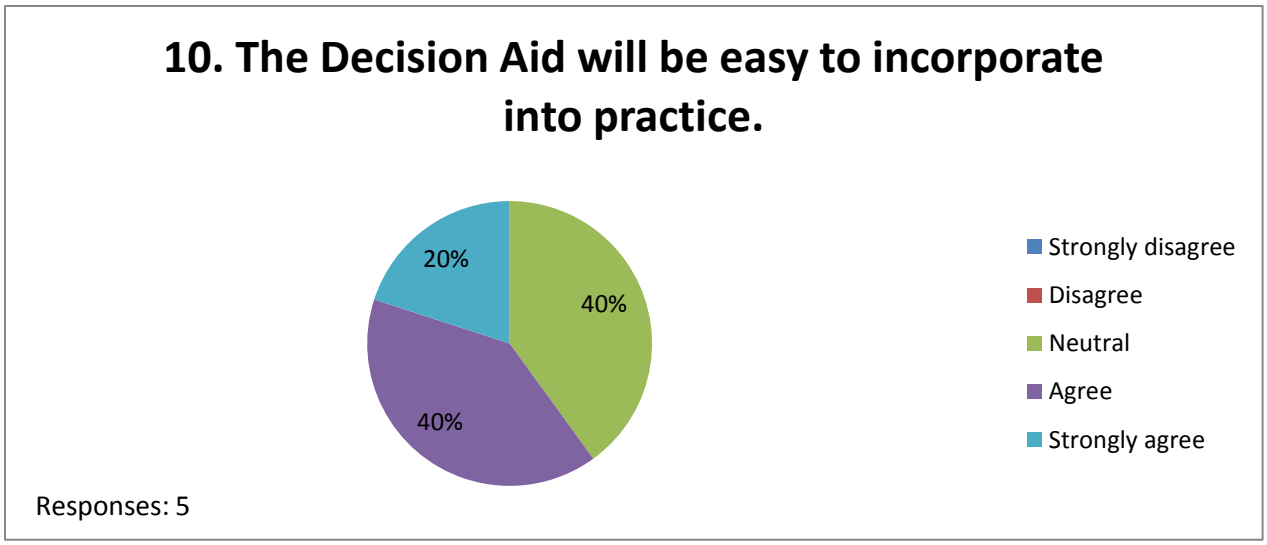

5. After viewing the PowerPoint, I feel more knowledgeable about lung cancer screening.
100%
Strongly disagree
Disagree
Neutral
Agree
Strongly agree
Responses: 5

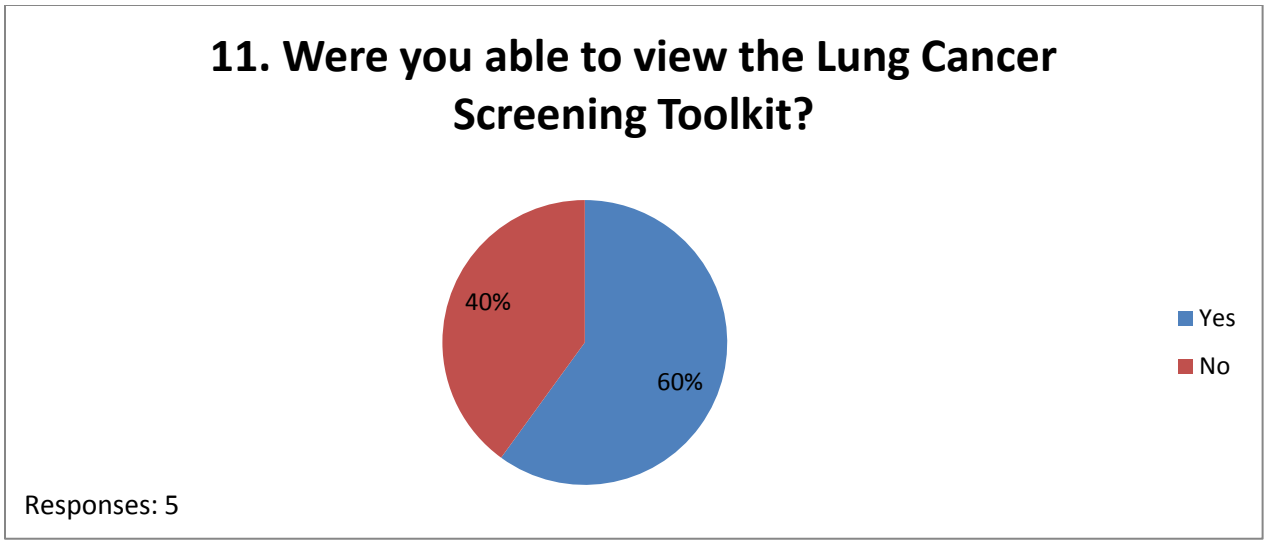

6. The Decision Aid will increase patient knowledge of lung cancer and screening.
20%
80%
Strongly disagree
Disagree
Neutral
Agree
Strongly agree
Responses: 5

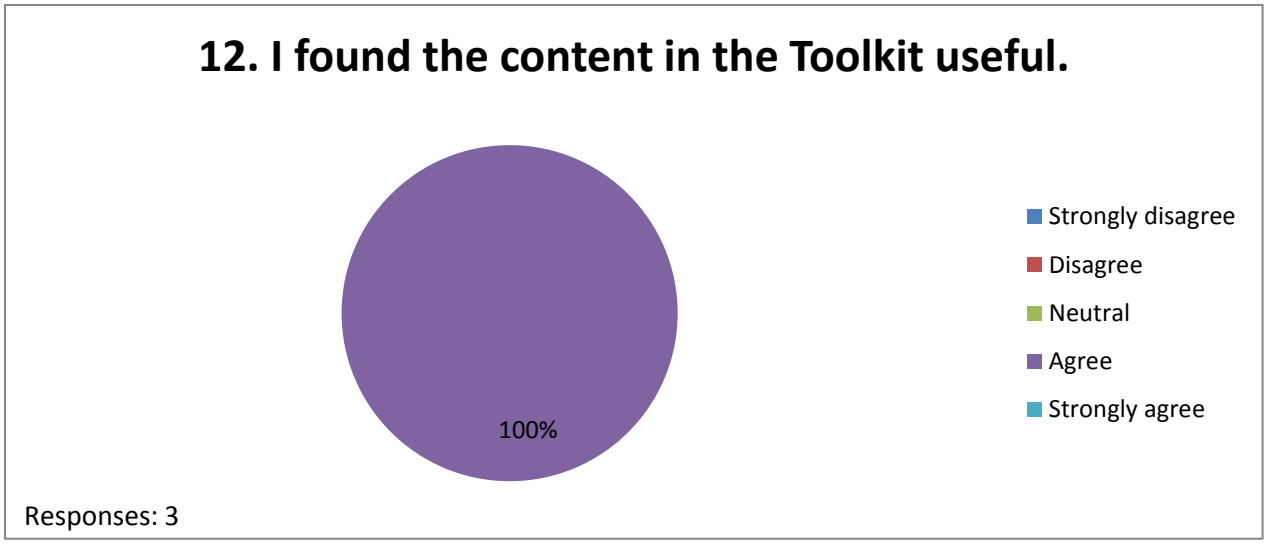

7. The Decision Aid will allow the patient to make an informed decision about screening for lung cancer.
20%
80%
Strongly disagree
Disagree
Neutral
Agree
Strongly agree
Responses: 5

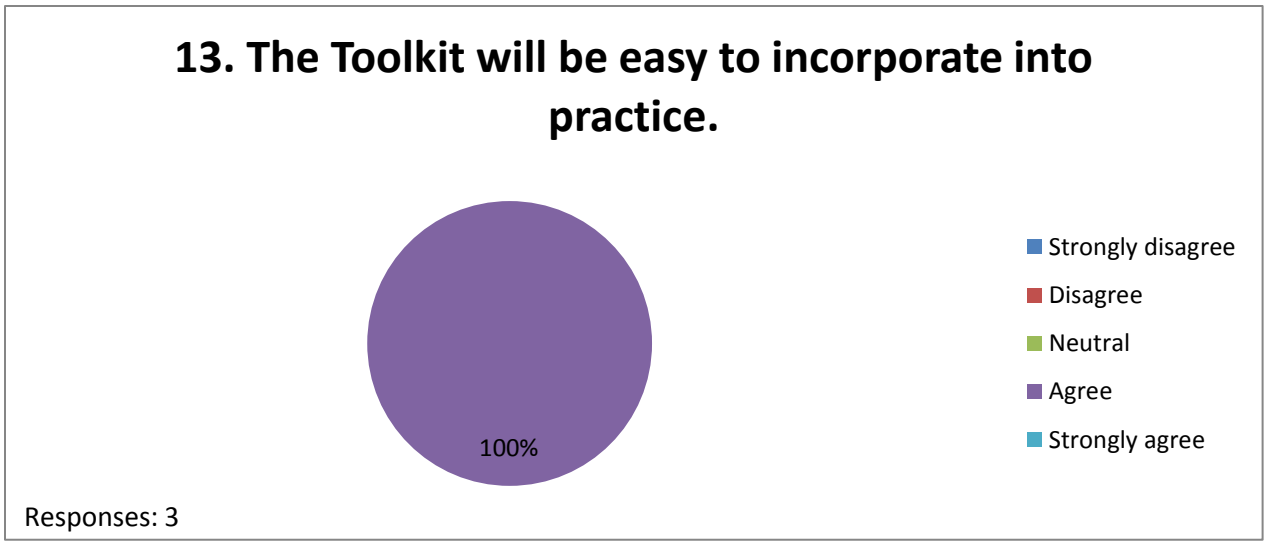

8. The Decision Aid is easy to read.
100%
Strongly disagree
Disagree
Neutral
Agree
Strongly agree
Responses: 5


9. The Decision Aid will help me to discuss lung cancer screening with patients.
20%
20%
60%
Strongly disagree
Disagree
Neutral
Agree
Strongly agree
Responses: 5


10. The Decision Aid will be easy to incorporate into practice.
20%
40%
40%
Strongly disagree
Disagree
Neutral
Agree
Strongly agree
Responses: 5


11. Were you able to view the Lung Cancer Screening Toolkit?
40%
60%
Yes
No
Responses: 5

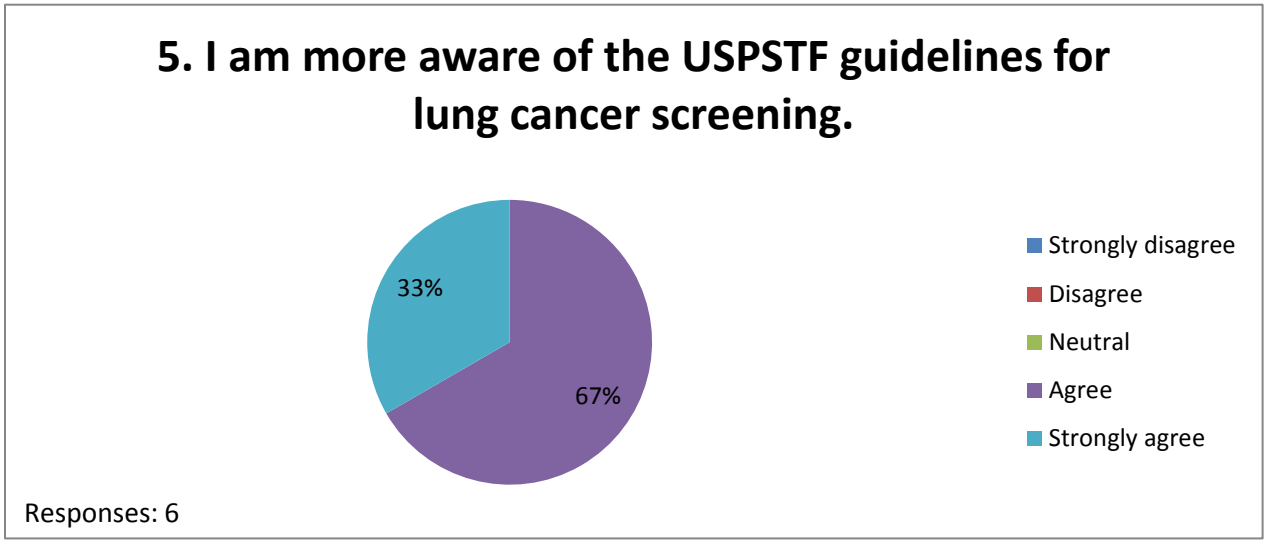

12. I found the content in the Toolkit useful.
100%
Strongly disagree
Disagree
Neutral
Agree
Strongly agree
Responses: 3

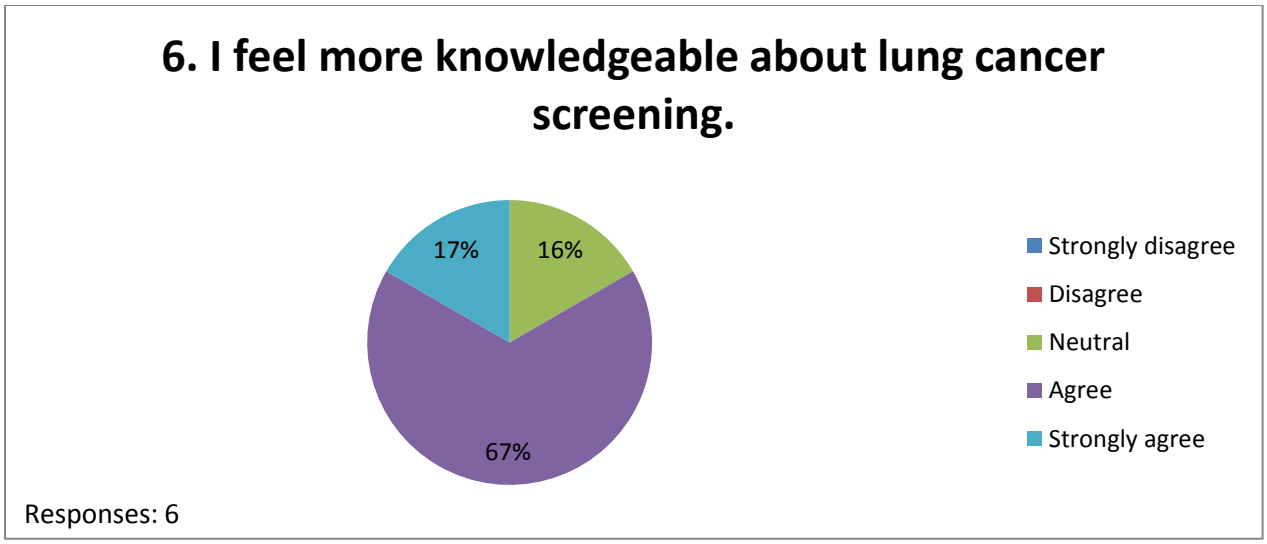

13. The Toolkit will be easy to incorporate into practice.
100%
Strongly disagree
Disagree
Neutral
Agree
Strongly agree
Responses: 3

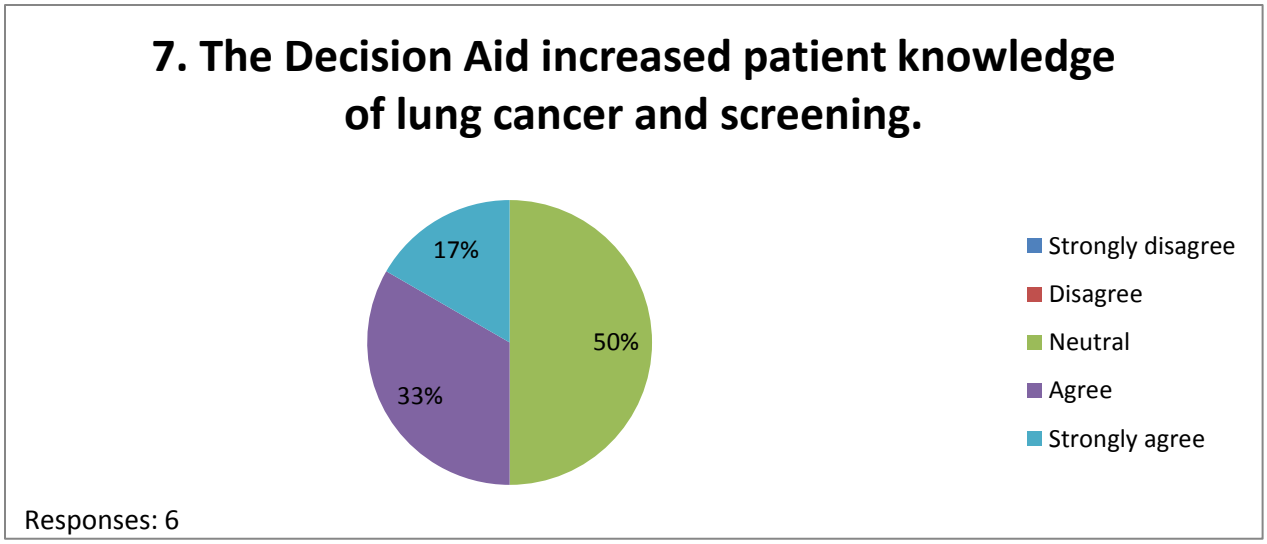
14. What did you like about the PowerPoint?
    a. That it was a brief concise review of the topic and the screening tool.
    b. Important information
    c. Gave stats and benefits, harms of the screening
    d. All the detailed info
    e. Clear and concise
15. How could the PowerPoint be improved? Is there any additional content that should be added?
    a. I think the one stat Dr D asked about number needed to harm would be good to add
    b. More interactive and shorter
    c. number needed to treat as well as number needed to harm (biopsies, stress, etc. from incidental findings as well as benign pulmonary lesions)
    d. No
    e. Not sure
16. What did you like about the Decision Aid?
    a. Straightforward for patient use
    b. Good info on it
    c. easy to read and understand
    d. The ease of its use
    e. I think I got a copy of it. It will be easy to understand
17. How could the Decision Aid be improved?
    a. NO specific feedback at this time
    b. Make more basic with info for low literacy and pictures
    c. n/a
    d. Not sure
    e. Not sure
18. What did you like about the Toolkit?
    a. I did not review the tool kit yet
    b. Good resource
    c. ease of use
    d. Easy to read info for the patient
    e. Not sure I got this
19. How could the Toolkit be improved? Are there other resources/information that should be included in the Toolkit?
    a. n/a since have not reviewed tool kit
    b. N/a
    c. no thoughts
    d. Maybe some additional websites
    e. Not sure
20. Please provide any additional comments about the Decision Aid, Toolkit, and/or PowerPoint presentation.
    a. Great job

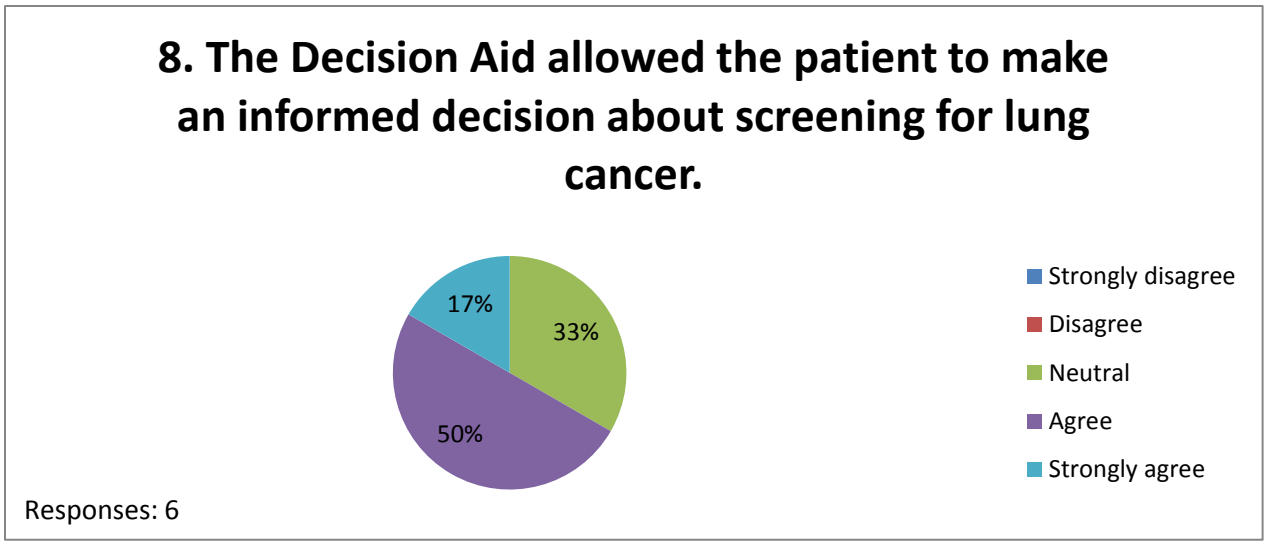
Two-Month Post-Educational Intervention Survey

1. How many referrals for lung cancer screening have you made over the past week?
    a. 0
    b. 0
    c. 0
    d. None
    e. None
    f. 0
2. How many referrals for lung cancer screening have you made over the past month?
    a. 0
    b. 0
    c. 0
    d. 1-2
    e. None
    f. 0
3. How many times did you use the Lung Cancer Screening Decision Aid with patients over the past two months?
    a. 0
    b. 0
    c. 0
    d. 2-3
    e. None
    f. 1
4. How many times did you use the Lung Cancer Screening Toolkit over the past two months?
    a. 0
    b. 0
    c. 0
    d. 2-3
    e. None
    f. 0




6. I feel more knowledgeable about lung cancer screening.
17%
16%
67%
Strongly disagree
Disagree
Neutral
Agree
Strongly agree
Responses: 6


7. The Decision Aid increased patient knowledge of lung cancer and screening.
17%
50%
33%
Strongly disagree
Disagree
Neutral
Agree
Strongly agree
Responses: 6


8. The Decision Aid allowed the patient to make an informed decision about screening for lung cancer.
17%
33%
50%
Strongly disagree
Disagree
Neutral
Agree
Strongly agree
Responses: 6

9. The Decision Aid was easy to read.

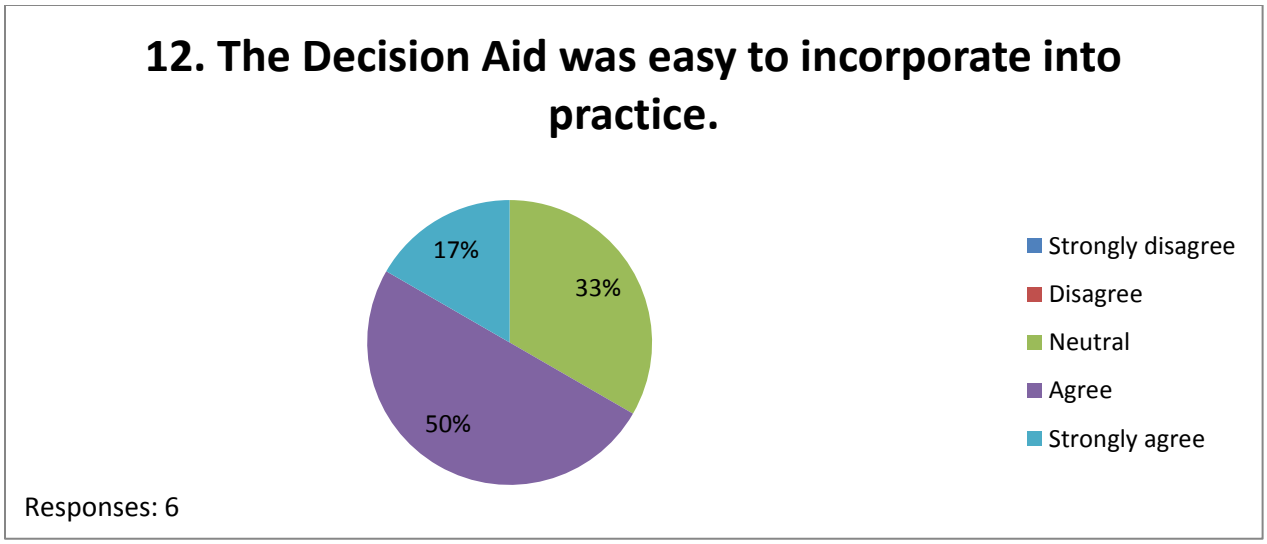
Responses: 6

10. If you used the Decision Aid with patients, do you feel that your patients accepted the Decision Aid?

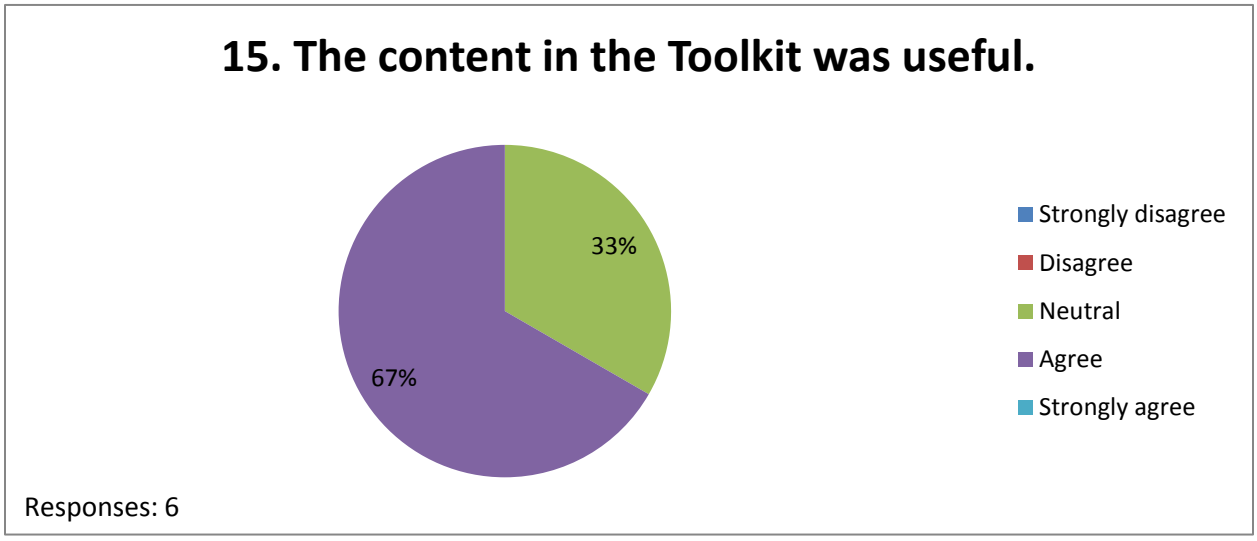
Responses: 6

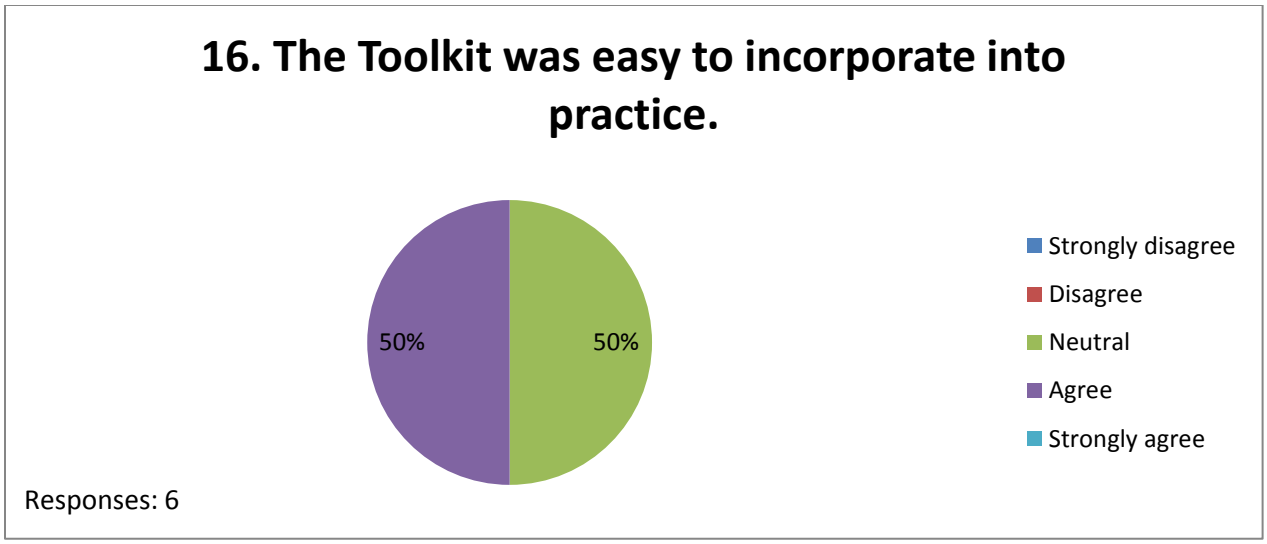
11. The Decision Aid helped me to discuss lung cancer screening with patients.

Responses: 6



13. Please discuss benefits to using the Decision Aid.
    a. Did not use the decision aid in the last 2months
    b. Potential ease of use.
    c. Efficient decision making for screening
    d. discussion is laid out
    e. Takes the guess work out of itp
    f. something the patient can take home and look at
14. Please discuss barriers to using the Decision Aid.
    a. DId not use the decision aid in the last 2 months
    b. Difficulty with bringing it up with a patient.
    c. N/A
    d. time consuming
    e. Time!!
    f. it may be over burdensome to some people, they may feel that the decision is then on them, rather than the doctor telling them what to do





17. Please discuss benefits to using the Toolkit.
    a. Did not use the Toolkit in the last 2 months
    b. Patients have an easy to understand piece of information about what could be a scary and confusing topic.
    c. Ease of accessibility to the data
    d. directs discussion
    e. More organized information
    f. did not use toolkit much
18. Please discuss barriers to using the Toolkit.
    a. Did not use the Toolkit in the last 2 months
    b. Having the right patient to use it with.
    c. Pt receptiveness
    d. takes time
    e. Time
    f. n/a
19. Please provide any additional comments.

Appendix E

IRB Determination Form

University of Massachusetts Amherst
108 Research Administration Building
70 Butterfield Terrace
Amherst, MA 01003-9242

Telephone: 545-3428 FAX: 577-1728
FAX: 577-1728

Human Research Protection Office
Research Affairs

MEMORANDUM

To: Courtney Cloonan, College of Nursing
From: Human Research Protection Office
Date: November 8, 2016

Project Title: ***Lung Cancer Screening with Low-Dose Computed Tomography: The Creation of a Toolkit to Assist Primary Care Providers in Screening and Educating High Risk Smokers***

IRB Number: 16-132

The Human Research Protection Office (HRPO) has evaluated the above named project and has made the following determination:

☐ The activity does not involve research that obtains information about living individuals and therefore does NOT require IRB review and approval.

☐ The activity does not involve intervention or interaction with individuals OR does not use identifiable private information and therefore does NOT require IRB review and approval.

☒ The activity is not considered research under the human subject regulations (Research is defined as "a systematic investigation designed to develop or contribute to generalizable knowledge.) and therefore does NOT require IRB review and approval.

☐ The activity is determined to meet the definition of human subject research under federal regulations and therefore DOES require submission of applicable materials for IRB review.

For activities requiring review, please see our web pages for more on types of review or submitting a new protocol. For assistance do not hesitate to contact the Human Research Protection Office at 545-3428 for assistance.