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Association of invitation to lung cancer screening and tobacco use outcomes in a VA demonstration project

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ABSTRACT

A potential unintended consequence of lung cancer screening (LCS) is an adverse effect on smoking behaviors. This has been difficult to assess in previous randomized clinical trials. Our goal was to determine whether cessation and relapse behaviors differ between Veterans directly invited (DI) to participate in LCS compared to usual care (UC). We conducted a longitudinal survey of tobacco use outcomes among Veterans (Minneapolis VA) from 2014 to 2015, randomized (2:1) to DI versus UC and stratified by baseline smoking status (current/former). Within the DI group, we explored differences between those who did and did not choose to undergo LCS. A total of 979 patients (n = 660 DI, n = 319 UC) returned the survey at a median of 484 days. Among current smokers (n = 488), smoking abstinence rates and cessation attempts did not differ between DI and UC groups. More baseline smokers in DI were non-daily smokers at follow-up compared to those in UC (25.3% vs 15.6%, OR 1.97 95%CI 1.15–3.36). A significant proportion of former smokers at baseline relapsed, with 17% overall indicating past 30-day smoking. This did not differ between arms. Of those invited to LCS, smoking outcomes did not significantly differ between those who chose to be screened (161/660) versus not. This randomized program evaluation of smoking behaviors in the context of invitation to LCS observed no adverse or beneficial effects on tobacco cessation or relapse among participants invited to LCS, or among those who completed screening. As LCS programs scale and spread nationally, effective cessation programs will be essential.

1. Introduction

The National Lung Screening Trial (NLST) demonstrated a 20% relative reduction in lung cancer mortality and a 6.7% relative reduction in all-cause mortality for individuals at high risk of lung cancer who were randomized to annual screening with low-dose computed tomography (LDCT) (Aberle et al., 2011). Because of these findings, lung cancer screening (LCS) has been endorsed by the U.S. Preventative Services Task Force (Moyer, 2014), the American Cancer Society (Wender et al., 2013), the American Thoracic Society, (Wiener et al., 2015) and others (Wood, 2015). Screening is recommended for individuals who meet criteria, including age 55–80, a cumulative 30 pack-year smoking history, and who are either current cigarette smokers or quit less than 15 years ago, repeated each year as long as the patient is eligible. In 2015, the Centers for Medicare and Medicaid Services announced that Medicare would cover LCS using LDCTs (Centers for Medicare, 2017). Despite these endorsements, uptake has been slow (Huo et al., 2017) in part because concerns remain about the potential unintended consequences of screening when delivered in a real-world setting.

One such concern from some stakeholders is that patients may view LCS as an alternative to abstinence from cigarette smoking (Wiener et al., 2015)— a form of the health certificate effect (van der Aalst et al., 2010; Ostroff et al., 2001). Others believe that screening represents a "teachable moment" that will increase quit rates (Taylor et al., 2007), as rates of cessation in participants in LCS trials have typically been higher than the general population. (Carreras and Gorini, 2017) Given the eligibility criteria, over half of those screened will be current smokers or recent quitters (Aberle et al., 2011). Therefore, any detrimental effect of screening on smoking cessation or relapse may mitigate the mortality benefit over time. Smoking cessation programs are a strongly recommended part of the implementation of LCS (Moyer, 2014; Wender et al., 2013; Mazzone et al., 2015) and the incorporation of tobacco cessation messaging can be an additional beneficial effect of

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participation in LCS. To date, most information on cessation behavior in the setting of LCS comes from secondary analyses of randomized controlled trials or small pilot studies (Clark et al., 2004; Ferketich et al., 2012; Filippo et al., 2015). Most of this data supports little overall effect of LCS on smoking cessation (Ashraf et al., 2014; Slatore et al., 2014; Zeliadt et al., 2015; Park et al., 2014). However, there are significant limitations when applying trial data to the real-world experience of LCS implementation. Because nearly all trial participants participated in some form of screening (e.g. chest X-ray), it is difficult to estimate the effect of LDCT LCS in comparison to no exposure to LCS at all. A significant proportion of patients who are offered LCS will decline to undergo the test (Kinsinger et al., 2017), and it is unknown what effect, if any, education about lung cancer risk and the benefits of screening may have on cessation behaviors, even among subjects who choose not to be screened. We undertook to examine tobacco behaviors in the setting of LCS program implementation.

Our objective was to examine the cessation and relapse behaviors in a cohort of Veterans who were eligible for lung cancer screening. We undertook this randomized program evaluation as part of an LCS demonstration project conducted within the Veterans Health Administration (VHA) from 2014 to 2015. We hypothesized that in comparison to Usual Care, a proactive, standardized invitation to participate in an LCS program would increase the likelihood of quitting among smokers and have a neutral effect on relapse among quitters.

2. Methods

We conducted a longitudinal survey at one facility (Minneapolis VA Health Care System [MVAHCS]) participating in the VHA Lung Cancer Screening Demonstration Project (Kinsinger et al., 2017). This National Demonstration Project was conducted at eight VA sites to provide guidance on key aspects of implementing LCS throughout the VHA system.

2.1. Participants

We used a national VHA electronic health record (EHR) algorithmic search to identify patients meeting the U.S. Preventive Services Task Force LCS criteria at the time of an appointment with their primary care provider. If a patient met the administrative inclusion criteria (age, no diagnosis of lung cancer, no chest CT in the past year), the algorithm activated a prompt in the EHR for the nurse checking in the patient to obtain a smoking history using a clinical reminder (Tobacco Pack Year [TPY] reminder) designed to identify candidates for LCS. Nurses recorded pack years (years smoked × average cigarettes per day), current smoking status, and time since quit for former smokers. The presence of a proactive clinical reminder identifying candidates for LCS had the potential to overwhelm limited screening resources. Therefore, a gradual, randomized roll-out was undertaken. Patients who were found to be eligible for LCS using the TPY reminder were randomly assigned to either be invited immediately to receive LCS (direct invitation, DI), or not (usual care, UC) in an unblinded fashion using a random number generator. For patients not initially offered screening, their reminder remained active until their subsequent primary care visits, when their primary care provider could then address LCS.

2.2. Interventions

Between 01/02/2014 and 08/15/2014 all LCS-eligible patients at the MVAHCS were prospectively randomly allocated at a 2:1 ratio to: (1) direct LCS invitation or (2) usual care provided by the primary care provider. A larger proportion of patients were invited to screening to provide more accurate estimates of response rates to an invitation to LCS. The patients in the direct invitation group received a mailed VHA-developed LCS decision aid and an invitation letter to call the screening coordinator for a discussion about enrollment in LCS. (See Appendices A and B.) The content of the decision aid was developed nationally by VHA educators, with content focused on the risks and benefits of screening, as well as the importance of quitting smoking and staying quit (Dept. of Veterans Affairs). Current smokers who called the LCS coordinator were offered referral to the comprehensive MVAHCS Tobacco Cessation Program, which is available to all MVAHCS patients and includes many options including patient education materials, individual and group behavioral therapy, and pharmacotherapy. Patients who did not contact the coordinator in response to the screening invitation received only the printed handout and letter. Patients in the usual care arm did not receive the educational materials or a proactive invitation to be screened. They could receive LCS at the request of their provider via an electronic consult to the screening program, and the content of these visits was at the discretion of the individual provider. Fewer than 1% were screened during the study period.

2.3. Survey procedures

We surveyed patients at three time points post-randomization, including baseline (T1), 6 months (T2), and 1 year or greater (T3). T3 survey was administered to all participants eligible, alive, and who had agreed to participate. This paper reports only on the third and final follow-up survey, administered from 8/13/2015 to 2/29/2016 to assess long-term tobacco use outcomes. Participants were mailed a study invitation letter that included a brief self-administered survey, and a postage-paid return envelope, with the option to complete by phone. They were offered $10 for the baseline survey, $20 for the second survey, and no stipend for the final tobacco outcomes. Non-respondents received telephone call reminders after 21 days with the ability to complete the survey over the phone. Subsequently, non-respondents received a second survey mailing. This survey study was approved by the MVAHCS Institutional Review Board.

2.4. Measures

2.4.1. Tobacco use outcomes

Tobacco use outcomes assessed on the final follow-up survey included 7-day and 30-day abstinence, frequency of smoking, and number of quit attempts in the past year. To assess smoking frequency, respondents answered the question, “Do you now smoke cigarettes every day, some days, or not at all?” Finally, to assess number of quit attempts, respondents reported how many times during the past year they had quit smoking intentionally for 24 h or longer.

A relapsed smoker was defined as a person who was a former smoker at baseline, but on the survey reported either that they smoked “every day”, or within the past 7 days or 30 days.

2.4.2. Participant characteristics

We collected the following clinical information from VHA medical records: baseline smoking status, TPY, LDCT completion (screened vs not screened), and, for those screened, LDCT completion date and result (no or benign nodule, nodule follow up necessary), age, gender, and race/ethnicity.

2.5. Statistical analysis

Given the inherent differences in smoking behavior between current and former smokers, and the corresponding different potential roles of the screening program in achieving or maintaining abstinence, we prespecified to stratify analyses by baseline smoking status. The analyses presented focus on the description and comparison of smoking status outcomes between those directly invited and those not directly invited to LCS. Further, within the direct invitation group, we performed exploratory analyses comparing outcomes between those who did and did not choose to be screened.

Pearson Chi-square tests were used to compare race (white and

minority) and gender between the randomized invitation condition groups, baseline smoking status groups, and combinations of smoking status and intervention assignment. These comparisons were made using all 1,388 randomized participants and also using only the 1,227 participants mailed the final survey. A Wilcoxon rank-sum test was used to compare continuous variables across groups, due to evidence that the distributions of those variables were not normal.

Our main analysis examined invitation group effects on self-reported smoking abstinence outcomes. We used logistic regression models to test for a relationship between smoking abstinence outcomes and invitation condition group, adjusting for age, gender, and race. Firth's penalized likelihood adjustment was used to address separability (quasi-complete separation) issues as warranted. Adjusted odds ratios with corresponding 95% confidence intervals were constructed from these models and are provided in the tables summarizing the results. A significance level of 0.05 was used for all tests of association.

3. Results

3.1. Study participants and baseline demographic characteristics

As previously reported in Fabbrini et al., (Fabbrini et al., 2018) 1,388 out of 6,133 (22.6%) unique primary care patients were determined to be likely eligible for LCS during visits with their primary care provider. (Fig. 1) Among these eligible patients, 744 (53.6%) were current smokers and 644 (46.4%) were former smokers. Smoking status and all other available baseline variables were balanced between the two arms (Table 1). Of these eligible patients, 926 were randomized to direct invitation and 462 to usual care. 118 patients died or were lost to follow-up, and so of the original 1,388 randomized, 1,270 patients were mailed the final follow-up survey. Surveys were returned by 979 participants (response rates 78.7% direct invitation group, 73.8% usual care). The median time from randomization to return of the final follow-up survey was 484 days (25th percentile 443 days; 75th percentile 566 days) or approximately 16 months.

3.2. Smoking behaviors among current smokers at baseline

Seven- and 30-day smoking abstinence rates at follow-up were 13.5% and 11.6% respectively for the direct invitation group and 9.4% and 6.9% for the usual care group, though these differences were not statistically significant (7-day aOR 1.52, 95% CI 0.77–3.55, 30-day aOR 1.90, 95% CI 0.90–4.02). More patients in the direct invitation arm did not smoke every day, (25.3 vs 15.6%, aOR 1.97, 95% CI 1.15–3.36). In both groups, approximately half of current smokers at baseline had made at least one quit attempt in the past 12 months. (Table 2).

3.3. Smoking behaviors among former smokers at baseline

Among former smokers at baseline, we observed a non-trivial rate of smoking relapse at follow-up. While the majority of former smokers remained abstinent, 17% overall relapsed to smoking as defined by

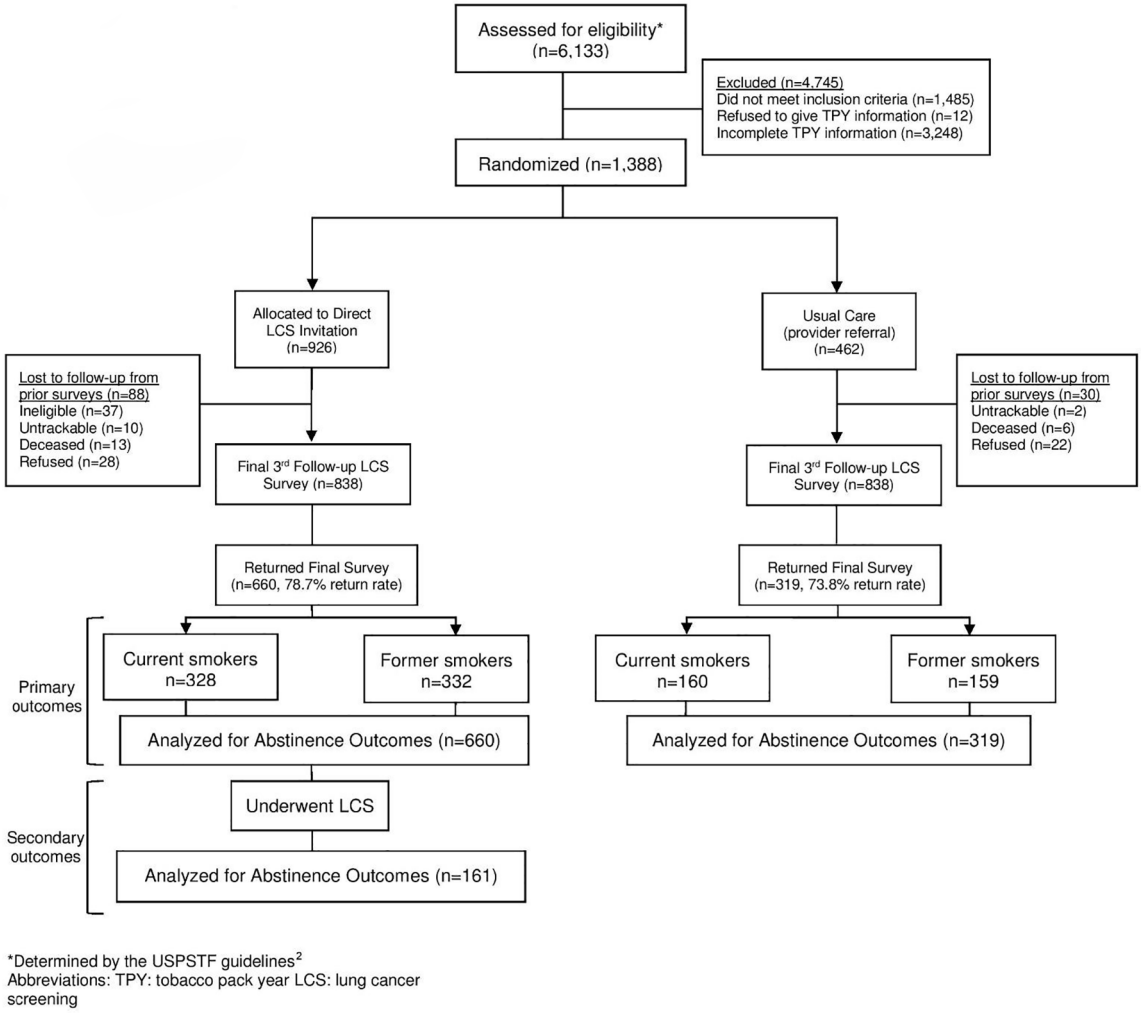

Fig. 1. Final study flowchart. Result of randomization and survey procedures.

Table 1
Baseline Characteristic, Overall, by Invitation Group, and by Baseline Smoking Status (n, %, unless otherwise stated).

	Usual Care (N = 319)			Direct Invite to Screen (N = 660)		
	Overall	Current Smokers (n = 160)	Former Smokers (n = 159)	Overall	Current Smokers (n = 328)	Former Smokers (n = 332)
Race						
White	265 (91.4)	128 (89.5)	137 (93.2)	557 (92.2)	265 (91.1)	292 (93.3)
Non-White*	25 (8.6)	15 (10.5)	10 (6.8)	47 (7.8)	26 (8.9)	21 (6.7)
Male gender	306 (95.9)	154 (96.3)	152 (95.6)	633 (95.9)	314 (95.7)	319 (96.1)
Age						
Mean ± SD	64.7 ± 4.9	64.1 ± 4.9	65.3 ± 4.8	64.7 ± 5.5	63.7 ± 5.5	65.7 ± 5.3
Median (IQR)	65 (6)	64 (7)	65 (4)	65 (7)	64 (8)	66 (6)
Pack Year						
Mean ± SD	53.0 ± 24.8	54.7 ± 24.9	51.3 ± 24.7	54.8 ± 25.4	53.5 ± 23.5	56.1 ± 27.2
Median (IQR)	45 (21.3)	47 (20)	45 (20)	48 (21.5)	48 (20)	48 (25.25)

* Non-white includes Black, American Indian, Native Alaskan, Asian, Hispanic, and multiracial.

cigarette use in the past 30-days. However, this was very similar between the direct invitation (16.8% relapsed) and usual care (14% relapsed) arms. (Table 2).

3.4. Smoking behaviors among those screened and not screened and by presence of a pulmonary nodule

Among subjects in the direct invitation arm, uptake of LCS was low, with 70 current smokers (21.3%) and 91 former smokers (27.4%) accepting the invitation and completing LCS. We performed exploratory analyses examining smoking outcomes among patients who did and did not choose to be screened, and by screen result. Twenty percent of current smokers completing an LDCT reported 7-day abstinence compared to 11.7% of current smokers not screened, and fewer current smokers at baseline who elected to be screened were smoking every day when compared to those who did not choose to be screened (67.1% vs 76.7%). Neither of these findings were significant. (Fig. 2a). There were no significant differences observed among former smokers. (Fig. 2b).

Among subjects who elected to be screened, 44/70 (62.9%) current smokers and 51/91 (56.0%) former smokers had a nodule in need of follow-up. For current smokers at baseline with a nodule present, 20.5% smoked not at all and 63.6% smoked every day at follow-up, compared to 15.4% and 73.1% among smokers without a nodule, though this finding was not significant. Surprisingly, fewer smokers with a nodule (50%) had tried to quit at least once in the past year compared to smokers without a nodule (73.1%) ($p = 0.003$). There were no significant differences in relapse rates by nodule status among former smokers undergoing screening.

4. Discussion

We assessed the effects of a direct, proactive invitation to participate in LCS with a printed decision aid on abstinence from and frequency of smoking among patients eligible for LCS, finding few significant effects on smoking behaviors. Our study is unique, as it evaluates tobacco behaviors within the little-studied group of patients who decline an offer of lung cancer screening and compares cessation and relapse patterns among an equivalent, randomly selected population in the absence of any exposure to LCS. Relatively few patients (approximately 1 in 4) chose to complete a lung cancer screening exam. We found that current smokers in the direct invitation group were significantly less likely to smoke every day, suggesting a slight positive impact on invitation to LCS. Though we observed no statistically significant differences in 7-day or 30-day abstinence between the two screening invitation groups our sample size may have been underpowered to detect a small difference in cessation rates.

Overall, our results favor a largely neutral effect of screening invitation on smoking cessation. Importantly, we did not find any evidence of a detrimental effect of screening on abstinence from tobacco. Among current smokers in the direct invitation group, there were more quitters among smokers who completed an LDCT compared to those who did not, though this was not statistically significant. We believe there may be two contributors to this difference. First, patients who elected to be screened may be more educated and engaged in health promotion behaviors, and therefore more motivated to quit smoking. They may more closely mirror the NLST trial participants who had a very high rate of observed smoking cessation in both the LDCT and chest X-ray screening arms (Aberle et al., 2011; Ostroff et al., 2001; Taylor et al., 2007; McMahon et al., 2008; Ashraf et al., 2009). Second, some of these patients had abnormal LDCTs, which have been repeatedly found to be associated with increased smoking cessation and motivation to quit (Tammemagi et al., 2014; Clark et al., 2016). There were fewer differences in relapse behaviors observed among former smokers, though both arms demonstrated a fairly high rate of relapse, likely higher than that observed in the NLST after a single year. Unfortunately, our decision aid did not include messaging specifically aimed at maintenance of abstinence. Messaging in the context of LCS should target maintenance of abstinence in addition to cessation. It should be noted that fewer than 1% of patients in the usual care arm were screened at the time of this survey. This was due to the fact that patients were surveyed as part of a staged, clinical roll-out. We have subsequently implemented a process using electronic clinical reminders to boost participation in LCS among all patients.

Our findings are consistent with prior research from RCTs which have shown mixed results for the impact of LCS on smoking behaviors. In the Danish LCS Trial the annual smoking rates were not significantly different between the LCS group and the control group over 5 years of follow-up (Ashraf et al., 2014). In the NLST, which did not include systematic smoking cessation programs, smoking cessation was associated with the degree of abnormality observed on the scan, with overall about 15% of patients in the screening arm quitting over the course of the first year. Rates of smoking declined steadily for participants in both arms throughout 5 years of follow-up (Tammemagi et al., 2014). This is in contrast to the Early Lung Cancer Action Program study, which found similar smoking abstinence rates among participants with a persistently negative LDCT result compared to smokers with a low to intermediate risk screening result (Anderson et al., 2009). The United Kingdom's randomized pilot trial of LCS found an increased odds of quitting among screened participants at 2 years (15%) when compared with controls (10%) (Brain et al., 2017 Oct). Only one trial, the Dutch-Belgium NELSON Trial, suggested potentially lower cessation rates among screened participants, however this effect did not persist in intention-to-treat analyses (van der Aalst et al., 2010). Several qualitative studies have suggested little or a possibly detrimental effect of LCS on the motivation to quit (Zeliadt et al., 2015; Park et al., 2014), which has so far not been borne out by the quantitative results. LCS may increase the likelihood of cessation for some patients and have a neutral or detrimental effect for others. The influence of screening on

Table 2
Outcomes of the Current Smokers and Former Smokers by Invitation Group (n, %) and adjusted odds ratios (AOR) with 95% confidence interval (CI); adjusted by age, gender, and race (white, non-white).

	Current Smokers at Baseline (n = 488)			Former Smokers at Baseline (n = 491)		
Outcomes	Direct Invite to Screen (n = 328)	Usual Care (n = 160)	AOR (95% CI)	Direct Invite to Screen (n = 332)	Usual Care (n = 159)	AOR (95% CI)
7-day abstinence*	44 (13.5)	15 (9.4)	1.52 (0.77, 3.55)	281 (84.6)	137 (86.7)	0.78 (0.43, 1.40)
30-day abstinence*	38 (11.6)	11 (6.9)	1.90 (0.90, 4.02)	272 (83.2)	135 (86.0)	0.74 (0.42, 1.31)
Current Smoking						
Not every day (vs every day)	83 (25.3)	25 (15.6)	1.97 (1.15, 3.36)	294 (88.6)	147 (92.5)	0.67 (0.33, 1.34)
Not at all (vs any)	41 (12.5)	13 (8.1)	1.61 (0.80, 3.23)	276 (83.1)	136 (85.5)	0.82 (0.47, 1.430)
At least 1 quit attempt (vs none)*†	169 (51.5)	78 (48.8)	1.14 (0.77, 1.71)	43 (75.4)	17 (77.3)	0.88 (0.25, 3.10)

* Some missing data present (3 missing 7-day abstinence, 8 missing 30-day abstinence, 1 missing occurrence of a quit attempt).
† For the former smokers, this considers only the 79 relapsed smokers.

Fig. 2. Frequency of smoking among patients in the Direct Invitation arm, stratified by decision to be screened. (a) displays frequency of smoking at follow-up among current smokers at baseline. (b) displays frequency of smoking at follow-up among former smokers at baseline.

subgroups of patients, such as those who decline or recent quitters, needs to be further elucidated in future prospective studies.

Smoking cessation increases both the effectiveness (Tanner et al., 2016) and cost-effectiveness (Villanti et al., 2013) of LCS. Our results suggest that LCS on its own is likely inadequate to increase cessation or decrease relapse among participants. Although programs should place a high priority on including effective tobacco treatment in LCS, the best way to do so remains unclear. A recent trial of an integrated telephone treatment program showed no benefit over usual care, leaving this question unanswered (Tremblay et al., 2019). The SCALE Collaboration (Smoking Cessation within the Context of Lung Cancer Screening) is a National Cancer Institute-sponsored initiative comprised of 8 ongoing trials looking at different methods of treating tobacco use in the context of LCS (Joseph et al., 2018). This collaboration, in which our site is a participant, will allow both between-trial comparisons of methodologies as well as pooling of relevant data, providing clinicians with more generalizable results. These results will allow programs to adopt evidence-based methodologies that will complement screening programs.

Due to the pragmatic nature of our evaluation, our study has limitations. The survey was conducted at one of eight sites participating in the VHA's demonstration project, included predominantly men and did not measure socioeconomic status, which may limit the generalizability of the findings. Current smoking status was determined by self-report and not biochemically verified. However, self-report of smoking status has been found to have high rates of agreement with urine cotinine among participants in lung screening trials (Tremblay et al., 2019). Finally, all subjects in both arms had access to the MVAHCS comprehensive tobacco cessation program. Differences in participation in tobacco treatment between arms was not captured by our study design. It is unclear what the effects would be on tobacco cessation and relapse behaviors for an LCS program implemented in a setting where usual care participants do not already have access to a wide range of smoking cessation resources. We had excellent response rates to our survey,

which was a strength of our study.

5. Conclusion and implications

In this evaluation of a clinical LCS population, we found no evidence to indicate that inviting smokers to participate in LCS via printed education materials, or completing an LDCT, has a large positive or negative effect on smoking behaviors. We observed a significant benefit of the program for only one of our measures, frequency of smoking. We did find an overall a non-significant trend towards increased cessation among current smokers invited to participate. This suggests that LCS programs may need to do more to encourage cessation among all patients, even those who decline screening. Future work needs to focus on quantifying the impact of LCS programs on cessation and relapse behaviors among all participants, including those who decline, and methods for integrating tobacco cessation into new and existing LCS programs. As LCS programs scale up and spread nationally, more intensive smoking cessation interventions should be coupled with LCS to magnify the benefits of lung cancer screening.

Author contributions

All authors have made substantial contributions to the conception and design, acquisition of data, or analysis and interpretation of data; contributed to drafting the article for important intellectual content; and provided final approval of the version to be published. There are no known conflicts of interest.

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Appendix A. Supplementary data

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