# © Effectiveness of Lung Cancer Screening Implementation in the Community Setting in the United States

Amy Copeland, MPH1; Angela Criswell, MA1; Andrew Ciupek, PhD1; and Jennifer C. King, PhD1

**QUESTION ASKED:** Can lung cancer screening be effectively implemented in nonacademic settings to detect lung cancer early, maximize benefits, and minimize harms?

**SUMMARY ANSWER:** Community-based lung cancer screening programs following best practices had comparable clinical findings to academic programs, while successfully fulfilling Centers for Medicare and Medicaid Services—mandated requirements for responsible screening. In both settings, the majority of lung cancers detected by low-dose computed tomography screening were diagnosed at stage I or limited stage.

**WHAT WE DID:** The  $\mathrm{GO}_2$  Foundation for Lung Cancer Screening Centers of Excellence network of lung cancer screening programs was surveyed to collect programlevel data about lung cancer screening workflow, barriers, and screening outcomes during 2016, the first full year of Medicare-covered lung cancer screening.

**WHAT WE FOUND:** In both community and academic centers, more than half of lung cancers were diagnosed at stage I or limited stage, demonstrating a clear stage shift compared with historical data. Lung-RADS results

were also comparable. There are wide variations in the ways that centers address the Centers for Medicare and Medicaid Services requirements for shared decision making and smoking cessation counseling. The most significant barriers to screening implementation were insurance and billing issues, lack of provider referral, lack of patient awareness, and internal workflow challenges.

**BIAS, CONFOUNDING FACTORS:** The lung cancer screening programs surveyed were all committed to following best practice protocols. Although there are now more than 600 Screening Centers of Excellence in the United States, the results may not be applicable to every program.

**REAL-LIFE IMPLICATIONS:** When lung cancer screening was initially recommended, there were questions about whether it could be carried out in nonacademic settings. These data indicate that responsible implementation is possible in the community and results in a meaningful stage shift for lung cancer diagnoses, and providers should support ongoing implementation of lung cancer screening efforts.

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Accepted on April 10, 2019 and published at jop.ascopubs.org on

May 31, 2019: DOI https://doi.org/10. 1200/JOP.18.00788



original contribution

# **Effectiveness of Lung Cancer Screening** Implementation in the Community Setting in the **United States**

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**PURPOSE** The National Lung Screening Trial demonstrated a 20% relative reduction in lung cancer mortality with low-dose computed tomography screening, leading to implementation of lung cancer screening across the United States. The Centers for Medicare and Medicaid Services approved coverage, but questions remained about effectiveness of community-based screening. To assess screening implementation during the first full year of CMS coverage, we surveyed a nationwide network of lung cancer screening centers, comparing results from academic and nonacademic centers.

METHODS One hundred sixty-five lung cancer screening centers that have been designated Screening Centers of Excellence responded to a survey about their 2016 program data and practices. The survey included 21 pretested, closed- and open-ended quantitative and qualitative questions covering implementation, workflow, numbers of screening tests completed, and cancers diagnosed.

RESULTS Centers were predominantly community based (62%), with broad geographic distribution. In both community and academic centers, more than half of lung cancers were diagnosed at stage I or limited stage, demonstrating a clear stage shift compared with historical data. Lung-RADS results were also comparable. There are wide variations in the ways centers address Centers for Medicare and Medicaid Services requirements. The most significant barriers to screening implementation were insurance and billing issues, lack of provider referral, lack of patient awareness, and internal workflow challenges.

**CONCLUSION** These data validate that responsible screening can take place in a community setting and that lung cancers detected by low-dose computed tomography screening are often diagnosed at an early, more treatable stage. Lung cancer screening programs have developed different ways to address requirements, but many implementation challenges remain.

J Oncol Pract 15:e607-e615. © 2019 by American Society of Clinical Oncology

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# INTRODUCTION

The National Lung Screening Trial (NLST) demonstrated a 20% relative reduction in lung cancer mortality with low-dose computed tomography (LDCT) screening.<sup>1</sup> The results of this landmark National Cancer Institute-funded clinical trial along with the development of the National Comprehensive Cancer Network Clinical Practice Guidelines for lung cancer screening<sup>2</sup> paved the way for public and private payer coverage of screening among those at risk and wider screening implementation.

In 2012, the GO<sub>2</sub> Foundation for Lung Cancer (GO<sub>2</sub>; formerly known as Lung Cancer Alliance) launched the National Framework for Excellence in Lung Cancer

Screening and Continuum of Care<sup>3</sup> to create a structure of best practices in lung cancer screening implementation to guide and hasten access to screening for those at high risk. From this, GO<sub>2</sub> developed a network of Screening Centers of Excellence (SCOEs), which has served as a defacto pilot project to demonstrate that quality screening in accordance with best practices can be implemented in the community

At the end of 2013, the US Preventive Services Task Force (USPSTF) gave LDCT lung cancer screening a grade B for those meeting specific high-risk eligibility criteria.4 This would ensure coverage without copays or cost sharing for all commercial plans covered by the

Author affiliations and support information (if applicable) appear at the end of this article.

Accepted on April 10. 2019 and published at jop.ascopubs.org on May 31, 2019: DOI https://doi.org/10. 1200/JOP.18.00788



Patient Protection and Affordable Care Act as well as for Medicaid expansion plans. The Centers for Medicare and Medicaid Services (CMS) followed suit, releasing a final National Coverage Determination in February 2015 covering eligible Medicare beneficiaries.<sup>5</sup>

Medicare coverage eligibility differed from the USPSTF recommendation only in age criteria (55 to 77 years v 55 to 80 years, respectively). However, CMS included several requirements addressing the process of screening. Central among these was a shared decision-making (SDM) requirement for all Medicare beneficiaries—the first instance of such a requirement as a condition for preventive service coverage. SDM includes eligibility confirmation through accurate and careful discussion of smoking history, cessation counseling and referral to assistive resources, a risk-benefits discussion, and explanation of follow-up and annual repeat screening adherence.<sup>5</sup>

In the background of the coverage debate was concern regarding whether the NLST results would be applicable in nonacademic, community practice. The Medicare Evidence Development and Coverage Advisory Committee stated, "Questions remain regarding... the likelihood that community based screening would replicate the positive results of the NLST without the safeguards of a rigorous randomized controlled trial, such as strict inclusion and exclusion criteria and training and accreditation of CT [computed tomography] reading." The American Academy of Family Physicians decided the evidence was insufficient to recommend lung cancer screening and noted that the NLST's favorable results "have not been replicated in a community setting."

This study aimed to examine implementation of lung cancer screening in the United States to determine whether community centers, defined here as those without an academic or university affiliation, can implement screening and adapt to complex CMS regulations while successfully detecting lung cancer at an earlier stage. To understand the successes and barriers of screening, the GO<sub>2</sub> SCOE network was queried about screening implementation during the first full year of the CMS-approved lung cancer screening policy.

# **METHODS**

To become a GO<sub>2</sub> SCOE, health care facilities must apply and attest to follow certain best practices. These include providing clear information on the risks and benefits of screening; complying with best practice standards controlling screening quality, radiation dose, and diagnostic procedures; working with a lung cancer multidisciplinary clinical team for follow-up and treatment when appropriate; including or referring to a comprehensive cessation program when applicable; reporting results to patients and referring providers in a timely manner; and having received or intending to receive designation as a lung cancer screening program through the American College of

Radiology (ACR). SCOEs provide data annually by both responding to a data collection survey and completing a required application update to maintain their designation.

The 2016 survey was designed with 21 closed- and openended quantitative and qualitative questions using SurveyMonkey (San Mateo, CA) and pretested with 10 members of the SCOE network to ensure feasibility. No individual patient data were requested, only aggregate program-level data.

The survey was distributed in waves to contacts at 276 SCOE programs representing 527 distinct screening sites between February 24 and August 15, 2017. One hundred sixty-five respondents completed both the survey and the required annual application update. In some cases, the respondent answered the survey for a single site within the SCOE, and in other cases, the respondent reported combined program data for multiple sites that have the same screening workflow.

### **RESULTS**

# Demographics of Lung Cancer Screening Centers in the United States

One hundred sixty-five SCOEs responded to the 2016 data collection survey and annual application update. Some respondents included data from multiple screening sites within their hospital network in their response, and others represented a single screening site. Respondents represented SCOEs in 34 states, with a concentration located in the US Census Bureau-defined Middle Atlantic and East North Central Regions (27% and 22%, respectively; Fig 1A). The majority of responding centers were community based, with 62% reporting having no university or other academic affiliation (Fig 1B), consistent with the full SCOE network, 60% of which is composed of communitybased programs. The number of screening centers in the United States is growing (Fig 1C). Slightly more than half of respondents (54%) initiated their screening program after the USPSTF screening guidelines were established. The lower number in 2016 reflects survey timing. Many programs initiated during 2016 did not respond as a result of insufficient data to report. One hundred forty-seven SCOEs were able to provide information about insurance coverage for their screening population. The majority of respondents (52%) reported that roughly half (40% to 59%) of patients screened by their program in 2016 were covered by Medicare (data not shown).

### Implementation of the CMS Requirements Among SCOEs

CMS requires that a counseling and SDM visit led by a physician or qualified nonphysician practitioner precede LDCT screening.<sup>5</sup> To understand implementation of this requirement, SCOEs were asked who handled SDM visits for Medicare beneficiaries. Nonacademic centers were more likely to rely on only primary care providers (PCPs) to perform SDM visits (52% v 40% of academic centers), whereas more academic centers had a screening team

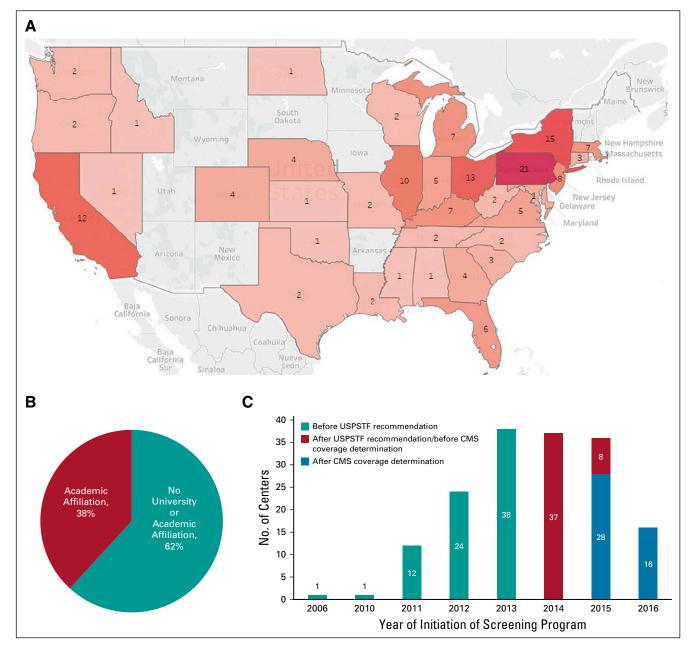


FIG 1. A snapshot of lung cancer screening in the United States, 2016. (A) Geographic distribution of the 165 Screening Centers of Excellence survey respondents. (B) Screening Centers of Excellence reported if they had an academic or university affiliation. (C) Time of initiation of each screening program and relationship to US Preventive Services Task Force (USPSTF) recommendation and Centers for Medicare and Medicaid Services (CMS) national coverage determination.

member perform this counseling (27% v 10% of non-academic centers; Fig 2A). Approximately one-fifth of both types of centers had a mix of PCP and screening team members perform the counseling. In write-in comments, some centers explained that it depended on whether SDM had already been performed, whereas others had a screening team member repeat the SDM discussion even if it had already been done by a PCP. Other programs reported that non-PCP referring providers (eg, pulmonologists) performed SDM counseling. Although CMS requirements only govern Medicare beneficiaries, 77% of all

centers required SDM visits for privately insured patients seeking screening (data not shown).

CMS also requires that smoking cessation services are available and offered to current smokers seeking screening.<sup>5</sup> To understand implementation of this requirement, centers were asked what types of smoking cessation services were offered. There was no significant difference in the types of cessation services offered between academic and nonacademic centers, with the three most common being referral to a quitline, cessation counseling within the

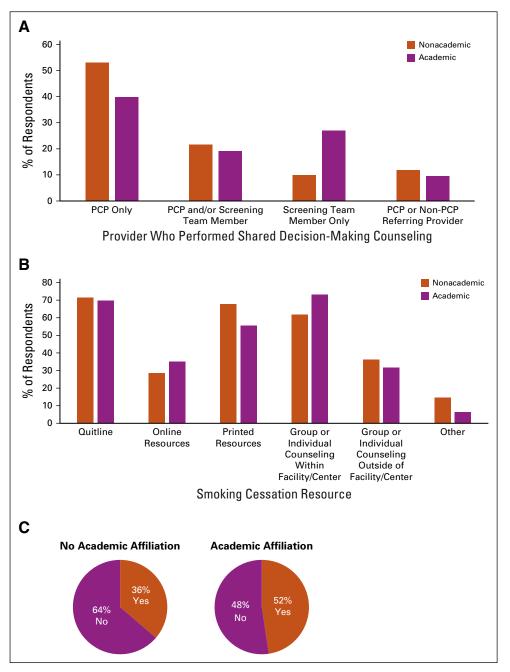


FIG 2. Implementation of Centers for Medicare and Medicaid Services (CMS) requirements. (A) Provider who performs shared decision-making counseling. (B) Smoking cessation resources provided to current smokers. Centers could choose multiple responses if applicable. (C) Information on whether screening centers follow up with current smokers after cessation counseling. PCP, primary care physician.

screening facility, and printed educational materials (Fig 2B). Notably, multiple responses were allowed, and only 27% of academic and 18% of nonacademic centers are using a single modality. Most programs are providing two to four distinct cessation resources for their current smokers undergoing screening. Academic-affiliated screening centers were more likely to follow-up with current smokers after screening to see if they had quit or needed additional resources than nonacademic centers (52% v 36%, respectively; Fig 2C).

# **LDCT Screening Results**

SCOEs are required to have systems in place to refer patients to a multidisciplinary care team when appropriate. To

understand how effective screening programs were at detecting lung cancer at a treatable stage, we asked about Lung Imaging Reporting and Data System (Lung-RADS) results and cancer diagnoses. ACR introduced Lung-RADS version 1.0 in April 2014 as a quality assurance tool to standardize lung cancer screening,<sup>5</sup> and it improved positive predictive value and decreased false-positive screens.<sup>8,9</sup> One hundred twenty-five centers (75 community centers and 50 academic centers) provided detailed Lung-RADS data on more than 40,000 LDCT scans performed in 2016 (Fig 3A). Some centers did not have the technical capacity or staff time to locate detailed data (many were using spreadsheets for patient tracking). Both

academic and nonacademic centers had similar rates of Lung-RADS 4A, 4B, and 4X findings, with 6.7% and 6.5% of scans having a category 4 designation, respectively. Academic centers reported more Lung-RADS category 2 scans compared with Lung-RADS category 1 scans, whereas nonacademic centers had an equal mix (Fig 3A).

SCOEs also reported total lung cancer diagnoses found by their program by type and stage of cancer. One hundred one centers (66 community centers and 35 academic centers) reported detailed data separated into baseline and annual scans on 529 lung cancer diagnoses initially identified by LDCT screening (Fig 3B). Some centers could not determine baseline versus annual scan because of the use of the same billing code. In addition, some screening programs are disconnected from oncology and pathology departments and thus did not have access to staging data. The majority of lung cancer diagnoses (80%) were made from baseline LDCT scans, as opposed to annual follow-up scans.

The most common diagnosis was stage I non-small cell lung cancer (NSCLC), representing 49% of diagnoses. The

stage and type distribution of lung cancers diagnosed through screening were similar between academic and nonacademic centers (Fig 3B). Not surprisingly, stage I NSCLC was more commonly found on annual scans than baseline scans (58% to 68% v 45% to 46%, respectively). Diagnosis of small-cell lung cancer (SCLC) was rare (10% of total diagnoses), with similar rates on both baseline and annual scans. When found, SCLC was more likely to be diagnosed as limited-stage disease than extensive-stage disease (62% of SCLC diagnoses were limited stage).

# **Barriers to Optimal Lung Cancer Screening**

One hundred forty-nine SCOEs responded to optional questions about barriers encountered in their programs during 2016. More than 50% of respondents reported insurance and billing issues, lack of patient awareness about screening availability, internal workflow issues, and provider referral barriers. Interestingly, only 35% of non-academic centers reported staffing and time limitations, whereas 53% of academic centers reported the same. Academic centers also reported more insurance and billing issues (74% of academic centers *v* 64% of nonacademic

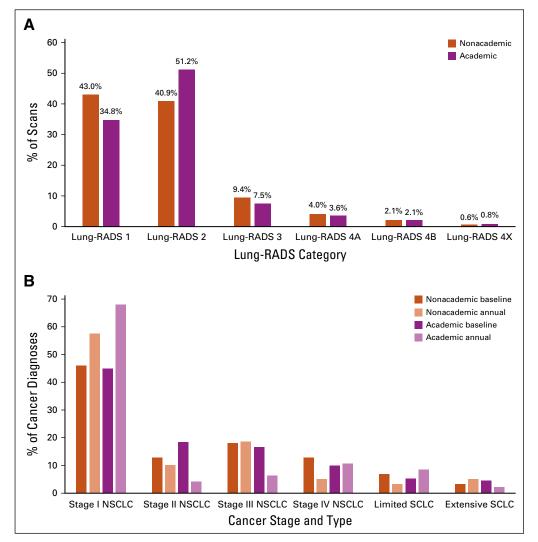


FIG 3. Lung cancer screening results. (A) Lung Imaging Reporting and Data System (Lung-RADS) score distribution category from more than 40.000 low-dose computed tomography scans (n = 24,249 nonacademic centers; n = 16,186academic-affiliated centers). (B) Percentage of each stage and type of lung cancer diagnosed at nonacademic centers (n = 272 cancer diagnoses at baseline screen; n = 59 diagnoses at annual screen) compared with academic-affiliated centers (n = 151 cancer diagnoses at baseline; n = 47 cancer diagnoses at annual screen). NSCLC, non-small cell lung cancer; SCLC, smallcell lung cancer.

centers). For other barriers reported, the percentages of academic and nonacademic centers reporting challenges were similar. Few centers (29% of nonacademic centers and 32% of academic centers) indicated that lack of patient interest in screening was a barrier.

#### **DISCUSSION**

There has been concern about the ability of nonacademic centers to implement lung cancer screening as safely and effectively as academic medical centers. In the NLST, only 30% of facilities identified as community cancer centers (C.D. Berg, personal communication December 2018). Subsequently, both the American Academy of Family Physicians<sup>7</sup> and the CMS<sup>6</sup> indicated concerns about whether there was adequate evidence to show that screening results from the NLST could be replicated in the community setting.

In this study, we not only demonstrate that lung cancer screening is happening in the community setting, but also that nonacademic screening programs are using similar protocols and are seeing similar findings as academic medical centers. We also show that both academic and nonacademic centers are effectively implementing CMS requirements, such as SDM and smoking cessation counseling. On the positive side, we found a shift toward early-stage diagnosis in both settings. Unfortunately, both types of facilities still struggle with similar barriers to implementation.

Upon initiation of data collection efforts, it became clear that screening programs collect data in different ways. For example, some programs were unable to differentiate between initial or baseline scans and annual scans because the medical billing code used for the service was the same for both. In addition, some coordinators did not have access to data separated by Lung-RADS scores or cancer staging data. Some health systems with multiple sites could only report the aggregate data from across multiple sites, whereas others reported data from single sites. This makes it difficult to determine the true response rate of the survey and the average number of patients screened per location. It also prevents in-depth analysis about geographic characteristics.

Because we surveyed a network of centers that attest to best practices, our data potentially skew toward having more successful outcomes. SCOEs are using best practice protocols, may have organized earlier, and may be screening more effectively than non-SCOE centers. For a broad view of screening, it would also be beneficial to look at screening practices outside of the SCOE network, which was outside the scope of this study. Fortunately for those at risk, the network used for this study now has more than 600 centers, and recent work has assessed the geographic availability of lung cancer screening at centers with either SCOE designation or ACR accreditation.<sup>10</sup>

Although communication about risks and benefits of lung cancer screening has always been a requirement for SCOEs, CMS required a counseling and SDM visit in their National Coverage Determination. Survey responses reflected ongoing challenges with meeting SDM requirements. Screening centers are implementing different workflows, with some relying on PCPs to perform this service, some relying on screening team members, and still others relying on both or on other types of care providers. Early guidance from CMS indicated this visit must be completed by a PCP, 11 although according to ACR, subsequent communication broadened the definition of who is required to perform SDM.<sup>12</sup> Because of the confusion and desire to ensure that SDM is completed, many programs integrated communication about risks and benefits at multiple points during the process regardless of reimbursement.

Earlier work assessed the readiness of SCOEs to implement smoking cessation. 13 In this study, most screening centers reported utilization of multiple resources, regardless of whether the center was academic or community based. This is a positive finding, given the complexity of smoking cessation. Evidence shows that smoking quit rates are higher when more than one method is used,14 so these results are consistent with best practices. Academic facilities were slightly more likely to use group or individual counseling within the facility or center, which may indicate that more internal resources exist to provide services on site. This is also a potential explanation for the higher percentage of patient follow-up after smoking cessation counseling at academic facilities. Coordinated research efforts are ongoing to understand the best methods to implement smoking cessation at the time of lung cancer screening. 15

The primary goal of screening for cancer is to catch the disease early when treatments are more effective. The NLST showed that screening for lung cancer with LDCT provided a significant survival benefit. The question of whether widespread adoption of lung cancer screening will result in earlier detection resulting in a stage shift and mortality benefit is central to defining the value of the service.

Importantly, there was not a significant difference in Lung-RADS results between academic and community centers. Both groups indicated a similar percentage of category 4B and 4X scans (2.1% and less than 1.0%, respectively) that would require follow-up beyond additional LDCT screening. Although the percentage of Lung-RADS category 2 scans were higher in academic facilities, both Lung-RADS category 1 and 2 scans require the same 12-month repeat LDCT, so the clinical outcome is the same for patients.

The cancer diagnosis data show that 49% of lung cancers found by screening programs were diagnosed as stage I NSCLC. An even higher percentage of stage I lung cancers was found on annual scans than at baseline, as would be

expected if LDCT screening was performing as anticipated (Fig 3C). This percentage of stage I lung cancer diagnoses is dramatically different from normal distribution of the disease. In a 2010 analysis of NSCLC diagnoses in the National Cancer Database, 26% of lung cancers were diagnosed at stage I, 28% were diagnosed at stage III when resection is often not possible, and 38% were diagnosed at stage IV. Similarly, the latest SEER statistics report 16% of lung cancers being diagnosed as localized disease versus 57% being diagnosed as distant or metastatic disease. <sup>17</sup>

Earlier research through the International Early Lung Cancer Action Program indicated a 92% survival rate in patients with resectable stage I lung cancer. <sup>18</sup> According to the seventh edition of the International Association for the Study of Lung Cancer staging guidelines for lung cancer, 5-year survival is 82% for stage IA lung cancer and 66% for stage IB lung cancer. In comparison, 5-year survival for stage IV lung cancer is 6%. <sup>19</sup> However, Woo et al<sup>20</sup> more recently questioned whether there was a true correlation to reduced lung cancer mortality. Although the magnitude of the mortality benefit may still be debated, the stage shift resulting from early detection is definitively seen at both academic and nonacademic facilities.

Lung cancer screening is still a relatively new service. Therefore, it is not surprising that programs face barriers to implementation. With Medicare coverage starting in 2015, many billing issues were still being worked out during our study period. For preexisting programs, the need to retrofit practices for new billing codes and screening prerequisites caused growing pains. Some of the internal workflow issues

reported included ensuring effective patient tracking, submitting required data to the ACR registry, electronic medical record integration to make patient tracking and ACR registry submissions more efficient, and integrating SDM visits.

The National Cancer Institute defines effective screening tests as those that can find cancer early, reduce the chance that someone who is screened will die of cancer, and have more potential benefits than harms.<sup>21</sup> Although mortality cannot be assessed in this study, the results indicate that lung cancer screening can be effectively implemented in community settings as appropriate CMS-mandated criteria for SDM and smoking cessation are being met to increase benefit and reduce harm and that there was a clear stage shift demonstrating the ability to find cancer early. This is a potentially lifesaving stage shift in diagnosis for the millions who are at risk for lung cancer.

Several opportunities exist to increase the impact of screening. With a shift in programs moving from a centralized model where patients directly contacted the cancer center to a model where the patient comes through a referring provider, there is a need to understand how best to coordinate care with and engage referring providers, as well as how to educate providers about requirements and patient eligibility. In addition, a recent report<sup>22</sup> showed that less than 2% of eligible smokers have been screened. That study and this one both identify lack of public awareness of lung cancer screening as a barrier for programs and an opportunity that should be embraced by the oncology community.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST AND DATA AVAILABILITY STATEMENT

Disclosures provided by the authors and data availability statement (if applicable) are available with this article at DOI https://doi.org/10.1200/JOP.18.00788.

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Final approval of manuscript: All authors
Accountable for all aspects of the work: All authors

#### ACKNOWLEDGMENT

Supported by the  $\rm GO_2$  Foundation for Lung Cancer. Presented, in part, at the 19th International Association for the Study of Lung Cancer World Conference on Lung Cancer, Toronto, Ontario, Canada, September 23-26, 2018, and at the 2018 National Lung Cancer Roundtable Annual Meeting, Washington, DC, December 10-11, 2018.

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#### **AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST**

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Foundation Medicine (Inst)

Research Funding: AstraZeneca (Inst)

No other potential conflicts of interest were reported.