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National Cancer Institute Smoking Cessation at Lung Examination Trials Brief Report: Baseline Characteristics and Comparison With the U.S. General Population of Lung Cancer Screening-Eligible Patients

Rafael Meza, PhD,[a] Jihyoun Jeon, PhD, MS,[a] Evelyn Jimenez-Mendoza, MS,[a] Yoonseo Mok, MPH,[a] Pianpian Cao, PhD, MPH,[a] Kristie L. Foley, PhD, MS,[b] Caroline Chiles, MD,[c] Jamie S. Ostroff, PhD,[d] Paul M. Cinciripini, PhD,[e] Jennifer Minnix, PhD,[e] Nancy A. Rigotti, MD,[f] Jennifer S. Haas, MD,[f] Kathryn Taylor, PhD,[g] Randi M. Williams, PhD, MPH,[g] Benjamin A. Toll, PhD,[h] Anne M. Joseph, MD, MPH[i,*]

[a]Department of Epidemiology, University of Michigan, Ann Arbor, Michigan
[b]Department of Implementation Science, Wake Forest School of Medicine, Winston-Salem, North Carolina
[c]Department of Radiology, Wake Forest School of Medicine, Winston-Salem, North Carolina
[d]Department of Psychiatry & Behavioral Sciences, Memorial Sloan Kettering Cancer Center, New York, New York
[e]Department of Behavioral Science, University of Texas MD Anderson Cancer Center, Houston, Texas
[f]Tobacco Research and Treatment Center, Department of Medicine, Massachusetts General Hospital and Harvard Medical School, Boston, Massachusetts
[g]Department of Oncology, Cancer Prevention and Control Program, Lombardi Comprehensive Cancer Center, Georgetown University Medical Center, Washington, District of Columbia
[h]Department of Public Health Sciences, MUSC Hollings Cancer Center, Medical University of South Carolina (MUSC), Charleston, South Carolina
[i]Department of Medicine, Masonic Cancer Center, University of Minnesota School of Medicine, Minneapolis, Minnesota

ABSTRACT

Introduction: The National Cancer Institute Smoking Cessation at Lung Examination (SCALE) Collaboration includes eight clinical trials testing smoking cessation interventions delivered with lung cancer screening (LCS). This investigation compared pooled participant baseline demographic and smoking characteristics of seven SCALE trials to LCS-eligible smokers in three U.S. nationally representative surveys.

Methods: Baseline variables (age, sex, race, ethnicity, education, income, cigarettes per day, and time to the first cigarette) from 3614 smokers enrolled in SCALE trials as of September 2020 were compared with pooled data from the Tobacco Use Supplement–Current Population Survey (2018–2019), National Health Interview Survey (2017–2018), and Population Assessment of Tobacco and Health (wave 4, 2016–2017) using the U.S. Preventive Services Task Force 2013 (N = 4803) and 2021 (N = 8604) LCS eligibility criteria.

Results: SCALE participants have similar average age as the U.S. LCS–eligible smokers using the 2013 criteria but are 2.8

years older using the 2021 criteria ($p < 0.001$). SCALE has a lower proportion of men, a higher proportion of Blacks, and slightly higher education and income levels than national surveys ($p < 0.001$). SCALE participants smoke an average of 17.9 cigarettes per day (SD 9.2) compared with 22.4 (SD 9.3) using the 2013 criteria and 19.6 (SD 9.7) using the 2021 criteria ($p < 0.001$). The distribution of time to the first cigarette differs between SCALE and the national surveys ($p < 0.001$), but both indicate high levels of nicotine dependence.

Conclusions: SCALE participants smoke slightly less than the LCS-eligible smokers in the general population, perhaps related to socioeconomic status or race. Other demographic variables reveal small but statistically significant differences, likely of limited clinical relevance with respect to tobacco treatment outcomes. SCALE trial results should be applicable to LCS-eligible smokers from the U.S. population.

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Keywords: Smoking cessation; Lung cancer screening; Clinical trials; Trial participant characteristics

Introduction

The National Cancer Institute administers the Smoking Cessation at Lung Examination (SCALE) Collaboration, a set of clinical trials that are testing smoking cessation treatment delivered in the context of lung cancer screening (LCS).[1] LCS is an important opportunity to deliver tobacco treatment, which augments the mortality benefit of screening[2,3] and is cost-effective.[4] SCALE is intended to facilitate data sharing and optimize knowledge gained from the set of clinical trials. The trials range in size (projected final sample sizes n = 308–1650) and test a variety of interventions ranging from individual therapies (behavioral and pharmacologic) to health system changes.

Current smokers who are LCS-eligible differ from smokers who have participated in smoking cessation trials in the general population because of age requirements (50 or 55 to 80 years old). LCS participants may be more proactive about their health (as indicated by receiving screening) than those who are not screened. These characteristics might improve the likelihood of quitting smoking. Conversely, older smokers have a longer duration of heavy tobacco use, may have tried to quit smoking numerous times in the past, and may be more refractory to smoking cessation interventions.[5,6] SCALE trials have the important purpose of investigating how best to implement evidence-based smoking cessation in the context of LCS and which treatments are most effective in the LCS population.

Eligibility criteria for LCS originally released by the U.S. Preventive Services Task Force (USPSTF) in 2013 included current and former smokers aged 55 to 80 years with a 30 or more pack-year smoking history, who currently smoke or have quit within 15 years. In 2021, the USPSTF eligibility criteria were expanded to ages 50 to 80 years and a 20 or more pack-year smoking history, who currently smoke or have quit within the past 15 years. The Centers for Medicare Services adopted these changes in 2022 (paying for LCS up to age 77 rather than 80).[7] Changes to the 2013 LCS eligibility criteria were largely prompted by limitations of the criteria to address disparities in lung cancer by sex and race.[3,8] Screening for lung cancer starting at an earlier age and a lower pack-year history should reduce racial disparities in screening eligibility, in particular for Blacks, who smoke fewer cigarettes per day (CPD) yet have a higher risk of lung cancer.[9–11] The new eligibility criteria also increased the proportion of LCS-eligible women who smoke fewer CPD on average or have lower pack-years.[12]

Therefore, SCALE trials are being conducted using LCS eligibility criteria that are evolving over time. The purpose of this analysis is to describe the baseline characteristics (demographics and smoking history) of SCALE trial participants and compare them to LCS-eligible current smokers in the general U.S. population, using data from three nationally representative surveys, applying both 2013 and 2021 LCS eligibility criteria. This will improve understanding of whether and how SCALE smoking cessation trial results, many of which will be available in the near future, can be generalized to the U.S. population of LCS-eligible individuals.

Materials and Methods

Seven SCALE trials volunteered to contribute data to this analysis and are included as authors. All participating trials have institutional review board approval. Deidentified trial data, as of September 2020, from the seven sites, were combined (n = 3614). Demographic measures include age, sex (male/female), race (White only, Black only, Asian only, Other race), ethnicity (Hispanic and non-Hispanic), education (eighth grade or less, ninth to 11th grade, high school graduate/general education development diploma, some college, college or above) and income per year (<$14,999, $15,000–$24,999, $25,000–$34,999, $35,000–$49,999, $50,000–$99,999 and ≥$100,000 U.S. dollar). Smoking variables include CPD and time to first cigarette (within 5 minutes, 6–30 minutes, 31–60 minutes, and after 60 minutes of waking).

SCALE participant data were compared with national survey data (pooled data from the Tobacco Use Supplement to the Current Population Survey [TUS-CPS] 2018–2019, National Health Interview Survey [NHIS] 2017–2018, and Population Assessment of Tobacco and Health [PATH] Study wave 4 2016–2017), which were the most contemporaneous with SCALE trial enrollment. Sample sizes of LCS-eligible current smokers from each national survey according to the USPSTF 2013 and 2021 guidelines were: TUS-CPS (2664 and 4691 respectively), NHIS (1160 and 2124), and PATH (979 and 1789). Variables in each national survey were recoded to match SCALE categories to the extent possible. To pool data from the three surveys, sample weights in each survey were reweighted according to their relative sample sizes.[13] More details are provided in the Supplementary Materials.

SCALE participant characteristics were compared with those of LCS-eligible current smokers in the general population on the basis of the USPSTF 2013 guideline (adults aged 55–80 y who have smoked at least 30 pack-years and currently smoke, n = 4803) and the USPSTF 2021 guideline (adults aged 50–80 y who have smoked at least 20 pack-years and currently smoke, N = 8604). Statistical differences between the characteristics of the SCALE trial and the national survey of LCS-eligible smokers were assessed using chi-square and t tests accounting for the standardized sample weights using the R package "weights" in R version 4.1.2.

Results

Demographic and smoking data for the seven SCALE trials are detailed separately in Supplementary Table 1. Data from the TUS-CPS 2018 to 2019, NHIS 2017 to 2018, and PATH Study wave 4 2016-2017 are detailed separately in Supplementary Table 2.

In comparison with national surveys using the USPSTF 2013 LCS eligibility criteria, SCALE participants are approximately the same age (SCALE 63.5 years versus national surveys 63.3 years, difference not statistically significant). SCALE has a lower proportion of men than in national surveys (51.6% versus 57.1%, $p < 0.001$). SCALE has a higher proportion of Blacks (11.6% versus 8.1%, $p < 0.001$) and a similar proportion of participants of Hispanic ethnicity. SCALE participants achieve a higher level of education than LCS-eligible current smokers in national surveys ($p < 0.001$) and have a somewhat higher income distribution ($p < 0.001$). CPD is significantly lower in SCALE participants, mean 17.9 (SD 9.2) versus 22.4 (SD 9.3), than in national surveys ($p < 0.001$). For SCALE participants, 73.9% smoke within 30 minutes of waking, compared with 77.9% for national survey participants ($p < 0.001$) (Table 1).

Discussion

We compared baseline data from seven SCALE trials to data from LCS-eligible individuals from the general population. There are statistically significant differences in some, but not all, variables between SCALE and LCS-eligible current smokers in the general population according to both the USPSTF 2013 and 2021 criteria. Interestingly, and consistent with the purpose of the changes to screening eligibility, many characteristics of SCALE participants are closer to those of LCS-eligible smokers from the general population according to the 2021 criteria, notably for the proportion of the Black race and average CPD. This suggests that the results of SCALE trials will be generalizable to the U.S. population. Sample sizes of all studies analyzed are quite large, which results in statistically significant differences even if the magnitude of the differences is small. Therefore, it is important to consider the clinical relevance of the findings. For example, differences in the proportion of male participants (SCALE 51.6% versus national surveys using 2013 criteria 57.1% and 2021 criteria 54.6%) are statistically significant but would not affect smoking cessation treatment recommendations.

Although there are significant differences in CPD between SCALE participants and LCS-eligible national survey respondents, both cohorts are heavier smokers than age-matched smokers in the general population.[13] This is to be expected, as LCS eligibility is on the basis of smoking history. The higher socioeconomic status (both education and income) of SCALE trial participants may also be related to lower CPD, in comparison to national survey data.[14] The increased prevalence of the Black race in SCALE trial participants may also explain lower CPD. Black individuals who smoke are lighter smokers and have lower mean pack-years by age 65 than White men and women who smoke.[15]

Results from both SCALE and the pooled national survey data regarding the time to first cigarette indicate that physical dependence on nicotine is highly prevalent among LCS-eligible current smokers. This suggests that tobacco treatment designed to be delivered in the context of LCS will be most successful if it includes evidence-based pharmacotherapy to address and treat nicotine withdrawal.

Overall, the results of this analysis suggest that SCALE trial outcomes will be highly applicable to the general U.S. population of LCS-eligible patients who smoke. Tobacco treatment is a critical aspect of a comprehensive LCS program. The SCALE trials will identify evidence-based cessation interventions delivered in the context of LCS that will enhance the benefits

Table 1. Demographic Characteristics of Lung Cancer Screening-Eligible Current Smokers in Pooled National Surveys (TUS-CPS 2018-2019, NHIS 2017-2018, PATH Wave 4 2016-2017) and Participants in the SCALE Trials

Variable	SCALE Trials (N = 3614)	National Surveys[a] (N= 4803) USPSTF 2013 LCS Criteria	p Value vs. SCALE	National Surveys[b] (N = 8604) USPSTF 2021 LCS Criteria	p Value vs. SCALE
Age (mean, SD)	63.5 (6.0)	63.3 (6.3)	0.18	60.7 (7.1)	<0.001
Sex, %			<0.001		<0.001
Male	51.6	57.1		54.6	
Female	48.4	42.9		45.4	
Race, %			<0.001		<0.001
White Only	85.4	88.5		86.0	
Black Only	11.6	8.1		9.9	
Asian Only	0.5	0.6		1.0	
Other race, including multiracial	2.5	2.8		3.1	
Ethnicity, %			0.40		<0.001
Non-Hispanic	96.8	96.6		95.1	
Hispanic	3.2	3.4		4.9	
Education, %			<0.001		<0.001
8th grade or less	4.4	5.3		5.0	
9th-11th grade	14.4	12.3		11.8	
High school graduate-diploma/GED	21.8	42.3		42.6	
Some college	38.2	29.6		30.0	
College or above	20.5	10.5		10.6	
Income, %			< 0.001		< 0.001
<$14,999 per y	21.7	26.0		25.3	
$15,000-$24,999 per y	13.5	14.8		14.5	
$25,000-$34,999 per y	11.5	13.2		12.4	
$35,000-$49,999 per y	12.8	13.5		13.4	
$50,000-$99,999 per y	28.9	23.5		24.7	
≥$100,000	11.5	9.0		9.7	
Cigarettes per d (mean, SD)	17.9 (9.2)	22.4 (9.3)	<0.001	19.6 (9.7)	<0.001
Time to first cigarette,[c] %			<0.001		<0.001
Within 5 min	29.6	28.9		27.0	
6-30 min	44.3	49.0		47.4	
31-60 min	16.2	14.8		17.0	
After 60 m	9.9	7.3		8.6	

[a]Screen-eligible criteria on the basis of the USPSTF 2013 guideline: adults aged 55 to 80 years who have smoked at least 30 pack-years and currently smoke. Unweighted counts in the pooled national surveys (n = 4803). All statistics were calculated by accounting for standardized individual sample weights.
[b]Screen-eligible criteria on the basis of the USPSTF 2021 guideline: adults aged 50 to 80 years who have smoked at least 20 pack-years and currently smoke. Unweighted counts in the pooled national surveys (n = 8604). All statistics were calculated by accounting for standardized individual sample weights.
[c]The information was only available in TUS-CPS and PATH for the national surveys.
GED, General Equivalency Diploma; LCS, lung cancer screening; NHIS, National Health Interview Survey; PATH, Population Assessment of Tobacco and Health; SCALE, Smoking Cessation at Lung Examination; TUS-CPS, Tobacco Use Supplement-Current Population Survey; USPSTF, U.S. Preventive Services Task Force.

of lung screening, improve its cost-effectiveness, and optimize resources.

CRediT Authorship Contribution Statement

Supplementary Data

Note: To access the supplementary material accompanying this article, visit the online version of the *JTO Clinical and Research Reports* at www.jtocrr.org and at https://doi.org/10.1016/j.jtocrr.2022.100352.

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