Implementing Lung Cancer Screening Under Medicare
The Last Chance to Get It Right?
Harold C. Sox, MD

In 2010, the investigators of the randomized National Lung Screening Trial (NLST) reported that annual screening with low-dose computed tomography (CT) reduced lung cancer mortality by 20% compared with screening with chest radiographs.1 Subsequently, several clinical practice guidelines recommended annual screening, and many insurers agreed to cover screening. Most recently, the US Preventive Services Task Force (USPSTF) recommended annual screening for 55- to 80-year-old individuals who had smoked at least 30 pack-years.2

The task force recommendation had special implications for Medicare because the Medicare Improvements for Patients and Providers Act of 2008 stipulated that any expanded coverage of preventive services had to be consistent with USPSTF recommendations. However, the initiative to expand coverage rested with the Centers for Medicare & Medicaid Services (CMS).

Since 1999, CMS has sought advice about insurance coverage from the Medicare Coverage Advisory Committee (MCAC) and its successor, the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). The MEDCAC hears testimony from invited speakers, engages in dialogue with topic experts, and votes. The MEDCAC met on April 30, 2014, to consider lung cancer screening. The average level of confidence in the evidence that the NLST results apply to Medicare-age patients was 2.2 on a scale of 1 (low) to 5 (high). The vote is advisory, and CMS staff will make the coverage decision. Meanwhile, members of both houses of Congress have urged CMS to cover lung cancer screening.

In this unfolding drama, the nation’s largest medical insurer is under pressure to cover lung cancer screening, but its advisory committee has serious concerns. Review of the transcript of the MEDCAC meeting reveals that the discussion was lively, comprehensive, and grounded in good science. Although the transcript did not include references, the evaluation of the key issues herein is supplemented with data from several studies. The MEDCAC discussion centered around 2 issues.

Concern About Screening Results in Medicare-Age Patients
Is it likely that the NLST evidence applies to Medicare-age patients? The NLST population was not representative of Medicare: 25% of the study population was 65 years or older; only 9% was older than 70 years, the median age at diagnosis of lung cancer.1 In contrast, 47% of all patients with lung cancer in the Surveillance, Epidemiology, and End Results database were 70 years or older.3 Moreover, older screening-eligible patients have more smoking-related comorbid conditions. In a study based on the National Inpatient Survey, the odds of in-hospital mortality after lung cancer surgery were 1.6-fold higher in Medicare patients than in commercially insured patients.4

In the MEDCAC discussion, the effect of screening on lung cancer mortality in the group aged 65 years and older was said to be statistically indistinguishable from that in the younger than 65 population; however, this comparison was inconclusive because the NLST did not enroll enough patients to test the hypothesis that the 2 subgroups were different.

The MEDCAC seemed to conclude that Medicare-age patients were more likely to experience harm from lung cancer screening, diagnosis, and treatment than were the NLST participants.

Concern About Nationwide Implementation of Screening
The MEDCAC was concerned about poor adherence to eligibility requirements in a large-scale implementation of lung cancer screening, so-called eligibility creep. Only 4 in 100 NLST participants with a positive scan had lung cancer; the rest did not benefit from screening because they did not have lung cancer but did experience the harms and anxiety of follow-up testing. If patients at lower risk of lung cancer were screened, they would be even less likely to have a true-positive finding on chest CT scan but would still experience the harms of a false-positive screening test. In lower-risk patients, the balance of harms and benefits would shift toward harm.

The MEDCAC was also concerned that physicians in low-volume facilities would be unable to match the high standard of care in the NLST. Lung cancer surgery in the NLST had a 1% mortality rate,1 lower than that by thoracic surgeons (2.3%), cardiac surgeons (3.4%), and general surgeons (4.0%) in the all-payer National Inpatient Survey.4

By the end of the discussion, it was clear why MEDCAC members had serious doubts about the application of the results in the NLST to Medicare-age people in community-based screening programs.

Why did the MEDCAC panel’s conclusions differ from that of the USPSTF? The main reason seems to be that the 2 panels addressed different screening populations. The USPSTF considered the evidence as it applied to the NLST study population, 90% of which was younger than 70 years. The evidence from this well-conducted clinical trial strongly indicated that screening caused a clinically and statistically significant improvement in lung cancer mortality in this study population.

The MEDCAC addressed the needs of high-risk smokers aged 65 years and older. The quality of the evidence is much lower than in the NLST study population, but suggests possi-
bly more adverse outcomes in Medicare patients and in community-based patients.

The CMS will issue its coverage decision soon. Whether it recommends coverage, Medicare patients do not have the evidence they need to make an informed, personal decision about lung cancer screening. What can the research community do to close the evidence gap in Medicare patients?

If CMS Decides Not to Cover Screening
CMS has the authority to cover the medical costs—but not costs of research—for patients enrolled in research about lung cancer screening in older smokers. The agency’s term for this strategy is “coverage under evidence development.” Ideally, a research sponsor would commission a study like the NLST but would enroll Medicare-eligible patients receiving screening paid for by CMS. More realistically, such patients would consent to enter a screening program in which their lung cancer-related events would be stored in a patient registry. The screening programs would be located in both academic medical centers and community settings to address concerns about screening outcomes in settings with lower patient volumes. The Veterans Health Administration (VHA) is conducting a pilot implementation of lung cancer screening in 8 VHA centers. The program includes elements of a patient registry. The VHA is setting a good precedent for how to roll out a new program. Medicare should take note.

A registry-based observational study could address a problem with current judgments about the balance of harms and benefits of screening, which are necessarily subjective because harms and benefits are typically measured in different units. If the study protocol included an assessment of the patients’ utilities, the benefits and harms can be expressed in the same units (quality-adjusted life-years) using modeling. In a modeling study, the net benefit of prostate cancer screening was positive or negative depending on the patient’s attitude toward the adverse effects of prostate cancer surgery.

If CMS Decides to Cover Screening
If CMS does cover screening, the problem will be maintaining high-quality services. CMS could pay for screening during a trial period while programs collect data on the outcome of recruitment, screening, diagnosis, and treatment of lung cancer. Programs would have to prove that they can sustain benchmark standards of performance for recruitment, screening, diagnosis, and treatment. Adherence to eligibility criteria could be measured simply by the trajectory of the program-wide incidence of lung cancer, which would decrease if adherence declined.

A Viewpoint by Volk and colleagues in this issue of JAMA suggests an alternative if CMS decides to cover screening: pay for screening only if patients engage in shared decision making. Shared decision making is a robust form of informed consent, in which the patient is an active participant in a 2-way conversation with a trusted health professional. In many cases, the patient uses a decision aid that describes the frequency of the possible outcomes and elicits the values he/she places on those outcomes. As carefully and thoughtfully articulated in the Viewpoint, shared decision making is especially suited to “close call” decisions, such as lung cancer screening in a Medicare patient with comorbid conditions.

Linking shared decision making to payment would motivate programs to inform patients fully and to improve program outcomes. Decision quality, an important measure of program performance, considers the patient’s knowledge of the decision alternatives, the level of decisional conflict, and whether the choice was consistent with how the patient valued the outcomes.

Conclusions
No one wants to repeat the experience with prostate cancer screening, which became a de facto standard of practice long before evidence from randomized trials signaled caution. The era of lung cancer screening begins with randomized trial evidence, but the potential for uncontrolled growth—and net harm—remains. If Medicare covers lung cancer screening, it must require routine reporting of recruitment, screening, diagnosis, and treatment of lung cancer from every screening site. The findings will help patients decide about screening, set benchmarks for evaluating programs, and inform policy about screening.

ARTICLE INFORMATION
Author Affiliations: The Dartmouth Institute for Health Policy and Clinical Practice, Geisel School of Medicine at Dartmouth, Lebanon, New Hampshire; Patient-Centered Outcomes Research Institute, Washington, DC.

Corresponding Author: Harold C. Sox, MD, Dartmouth Institute for Health Policy and Clinical Practice, Geisel School of Medicine at Dartmouth, 31 Faraway Ln, West Lebanon, NH 03784 (hsox@comcast.net).

Conflict of Interest Disclosures: The author has completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr Sox reporting chairing the US Preventive Services Task Force and later was the first chair of the Medicare Coverage Advisory Committee. He is employed by the Patient-Centered Outcomes Research Institute (PCORI) and is the project officer for a PCORI-funded study for which Dr Volk (reference 9) serves as the principal investigator.

REFERENCES