Balancing the Benefits and Harms of Low-Dose Computed Tomography Screening for Lung Cancer: Medicare's Options for Coverage

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On 30 April 2014, the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) convened to weigh the evidence for low-dose computed tomography (LDCT) screening for lung cancer. Many were shocked by the outcome: a vote of low confidence about whether the benefits of LDCT screening would outweigh harms among Medicare beneficiaries in a community setting. After all, LDCT screening was shown to reduce mortality in the NLST (National Lung Screening Trial) (1), a multicenter randomized trial enrolling more than 53 000 participants at high risk for lung cancer, and multiple guidelines now recommend LDCT screening for high-risk persons. Indeed, on the basis of a grade B recommendation from the U.S. Preventive Services Task Force (2), the Patient Protection and Affordable Care Act (Affordable Care Act) requires private insurers to cover LDCT screening beginning in 2015 for persons aged 55 to 80 years who have smoked within the past 15 years and have at least 30 pack-years of tobacco exposure. Given the heavy burden of lung cancer among Medicare beneficiaries (both incidence and mortality peak in this population), most expected Medicare to follow suit to capitalize on the potential benefits of screening.

Yet, there are important reasons for caution before widespread implementation of LDCT screening among Medicare beneficiaries. The data in this population are limited: Only 25% of NLST participants were older than 65 years, and none were older than 74 years. Meanwhile, the harms of screening are real and likely to be pronounced among older persons. False-positive results (typically pulmonary nodules) increase with age (3). Older persons have higher complication rates from biopsy of pulmonary nodules (4) and higher postoperative mortality from resection of nodules (5). These harms may be magnified in the community, where interpretations of screening CT results, use of invasive procedures, and complications of such procedures can vary widely (3, 4), with resulting harms from overtesting and overtreatment (6). Moreover, as the competing risk for death from other causes increases with age and comorbid conditions, the potential benefit of extending life through LDCT screening diminishes. And, of course, there are cost considerations. There will be an inevitable and substantial financial impact to the Centers for Medicare & Medicaid Services (CMS) of implementing LDCT screening, with the attendant expenses of downstream evaluation and treatment of screen-detected nodules, extrapulmonary incidentalomas, and cancer (7).

Despite these concerns, there are reasons to believe LDCT screening can be implemented safely and effectively in the community. Several early-adopting sites have thoughtfully designed LDCT screening programs with appropriate precautions in place to minimize harms and maximize benefits (8–10). A particularly well-designed model is the Veterans Health Administration's 8-site demonstration project of LDCT screening, which includes a plan for careful data collection and evaluation to further inform how benefits and harms of LDCT screening are balanced in the real-world setting.

What are the possible implications of the MEDCAC vote for Medicare beneficiaries and their clinicians? In perhaps the worst-case scenario, CMS may decline to cover LDCT screening, which would surely increase socioeconomic and age-based disparities in lung cancer outcomes. Persons younger than 65 years would be eligible to receive LDCT screening through the Affordable Care Act mandate. Older persons with the ability to pay out of pocket could do so (many programs already offer LDCT screening on a fee-for-service basis). Meanwhile, economically disadvantaged seniors—the same individuals who already have a disproportionate risk for developing and dying of lung cancer due to higher tobacco use and delays in receipt of care—would be either deprived of the opportunity of early detection and treatment or forced to prioritize health care expenditures (for example, LDCT screening vs. prescription medications).

Another possibility is a CMS determination of coverage with evidence development. In this scenario, CMS would require medical centers to collect data on persons having LDCT screening in a standardized registry, similar to that being used in the Veterans Health Administration demonstration project. After a period of data collection (which could last years), CMS would review the accumulated evidence and decide whether LDCT screening should receive a determination of broad coverage or no coverage. The downside of this option is that there is no guarantee that appropriate protocols to minimize harms of screening would be implemented and remain in place after the period of coverage with evidence development ended.

A third, perhaps optimal, option would be for CMS to offer coverage of LDCT screening only when it is done in facilities that are certified as comprehensive, patient-centered programs designed to maximize benefits and minimize harms. Professional societies, such as the American College of Radiology, American Thoracic Society, and American College of Chest Physicians, are already collab-

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orating to define the quality standards that LDCT screening programs should meet. Critical components may include 1) rigorous procedures to ensure that only high-risk persons who meet eligibility criteria are screened, thus avoiding the iatrogenic harms that occur when screening is extended to low-risk persons unlikely to benefit; 2) shared decision making to inform individuals of their personalized risk for lung cancer and to help them weigh the tradeoffs of LDCT screening before deciding whether to proceed; 3) integration of smoking cessation services (because quitting smoking is the best way to reduce the risk for lung cancer death); 4) a comprehensive, multidisciplinary process for not just the initial screening but also for protocolized evaluation of screen-detected abnormalities; and 5) maintenance of a registry of screened patients by a program coordinator (often a nurse) to ensure that appropriate algorithms are followed throughout the duration of screening and downstream nodule evaluation (6). Future research would be essential to assess the impact of a certification process on the quality and safety of and access to LDCT screening in the community.

The advent of LDCT screening ushers in a new era, with the exciting opportunity to reduce mortality from the leading cause of cancer death. However, the tradeoffs of LDCT screening are real, and programs must be carefully designed to maximize benefit while reducing harms to screened persons. To avoid the hard lessons learned from overzealous implementation of prostate cancer screening, we must get implementation of LDCT screening right from the outset. A CMS determination that LDCT screening will only be covered in qualified facilities may provide the perfect opportunity to do so.

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