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Review

Implementing lung cancer screening: the US experience

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The reduced lung cancer mortality observed with low-dose computed tomography (LDCT) screening in the National Lung Screening Trial (NLST) has led to annual screening in the United States as a covered benefit by both private insurers and the federal health insurance programme, the Centers for Medicare and Medicaid Services. Reimbursement for screening requires data submission to a federal registry on all individuals, whether privately or federally insured. Data must document individual patient eligibility as well as shared decision-making regarding the benefits and risks of LDCT screening, smoking cessation counselling, and the importance of annual screening. Beyond these requirements lie opportunities to maximise the benefits of screening in the radiology setting. Individuals eligible for screening account for a minority of those diagnosed with lung cancer in the US; the evidence needed to improve patient selection must be collected systematically for both screen-detected and incidentally detected lung nodules. Current nodule management and tracking guidelines reduce the false-positive rates observed in the NLST, but fall short in their ability to correctly classify nodules as benign or malignant. Smoking cessation is inadequately managed in most busy clinician practices. As a common nidus for tobacco-associated lung diseases, imagers are uniquely poised to collect the longitudinal data to better inform screening eligibility and to improve indeterminate nodule management, while maximising the setting of screening to motivate and provide smoking cessation. By re-engineering the notion of imaging practice, radiologists can be major contributors to lung cancer early detection and mortality reduction.

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Introduction

The primary results of the National Lung Screening Trial (NLST) initiated a sea-change in the approach to early detection and mortality reduction from lung cancer in the US.¹ Prior to this time, lung cancer screening was recommended by no medical professional organisation. The

observation that three annual screens with low radiation dose computed tomography (LDCT) resulted in a 20% lung cancer mortality reduction relative to chest radiographic screening in older, moderate-to-heavy cigarette smokers, ultimately led to annual LDCT screening as a covered preventive benefit by both private insurers and the Centers for Medicare & Medicaid Services (CMS), the federal health insurance programme for individuals 65 years of age and older.^{2,3}

Coverage by CMS has substantial eligibility requirements, among which are: asymptomatic individuals aged 55–77 years with a tobacco smoking history ≥ 30 pack-years (1 pack-year = smoking one pack per day for 1 year; one pack = 20 cigarettes). Individuals may be

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current or former smokers with ≤ 15 years since quitting (YSQ).³ Private insurers must cover screening costs in similar current and former smokers up to age 80 years. The referral for LDCT screening must include documentation that the order occurs during a screening counselling and shared decision-making visit that includes: (a) determination of eligibility based on age, symptoms, smoking status, pack-years, and YSQ; (b) shared decision-making using decision aids to include discussion of the benefits and harms of screening, follow-up diagnostic testing, over-diagnosis, false-positive rates, and total radiation exposure; (c) counselling on the importance of adherence to annual lung cancer LDCT screening, as well as the impact of comorbidities and ability or willingness to undergo diagnosis and treatment; and (d) counselling on the importance of continued cigarette smoking abstinence if a former smoker, or smoking cessation if a current smoker. There are eligibility requirements of the interpreting radiologist(s) as well as the imaging facilities that perform LDCT screening, the latter of which include: (a) performing LDCT with a volumetric CT dose index (CTDIvol) of ≤ 3 mGy; (b) using a standardised lung nodule identification, classification, and reporting system such as the American College of Radiology (ACR) Lung CT Screening Reporting and Data System (Lung-RADS); (c) making smoking cessation interventions available for current smokers; and (d) collecting and submitting screening data to a CMS-approved registry for all LDCT screening examinations, including those covered by private insurers.

Although lung cancer screening with LDCT was initiated at several institutions following the publication of the NLST primary endpoint, the CMS coverage decision was issued 5 February 2015. Since this time, over 2,500 institutions in the US have registered to become sites by the ACR Lung Cancer Screening Registry, which is currently the only registry approved by CMS.⁴ Satisfaction of this designation requires that each site submit data related to individual eligibility, other risk factors for lung cancer, screening image acquisition and reconstruction parameters, screen interpretation and recommendations, and various outcomes on all screened individuals at the site. In this way, the data necessary to understand the characteristics of patients entering screening, screening compliance, the performance of interpretation guidelines, and ultimate outcomes can be collected across the US.

Determining eligibility

A host of logistical and operational challenges are associated with lung cancer screening. As a new screening intervention, many primary and subspecialty care clinicians are unaware of the eligibility criteria and strict requirements for shared decision-making in order to satisfy screening reimbursement. For many programmes, this has resulted in a moderate number of screening referrals for individuals who neither satisfy age and smoking criteria nor have undergone shared decision-making. Some programmes have addressed this by requiring that all

individuals referred for screening meet first with a trained healthcare provider to determine eligibility and to ensure that benefits and harms have been appropriately discussed. This has the advantages of guaranteeing compliance with CMS requirements, but works to the inconvenience of the individual patient unless the screening examination can be completed in the same setting. Using the benefits of order entry within electronic medical records, some programmes have implemented a series of prompts that require specific responses prior to ordering LDCT screening examinations. Although intended to document satisfaction of CMS requirements at the time of order entry, the validity of responses is at the discretion of the ordering physician, and many patients are ultimately found to be ineligible or uninformed about the balance of benefits to risks of screening. How this dilemma is addressed varies across programmes, but two essential requirements are to provide aggressive education to provider groups and to provide decision support tools that can be used during shared decision-making. Some institutions have adopted hybrid approaches in which patients may be referred for either pre-screen counselling or directly for screening. Approaches to satisfying eligibility criteria necessarily depend upon institutional preferences, culture, and available resources.

Beyond the challenges of meeting current screening eligibility criteria is the concern that qualified individuals account for fewer than one-third of individuals in the US who develop lung cancer based on data from the Surveillance, Epidemiology and End Results (SEER) database.⁵ More informed approaches could include the expansion of criteria to include other known risk factors, as has been promulgated by the National Comprehensive Cancer Network (NCCN), or the use of mathematical models of risk such as the Prostate-Lung-Colorectal-and-Ovarian (PLCO) 2012 model, which has been shown to result in higher yields of lung cancer diagnosis while screening fewer individuals.^{6–8} Given current reimbursement constraints, more optimal eligibility criteria will require that imaging centres adopt standardised approaches to the assessment and management of both screened-detected and incidentally-detected nodules, capturing known risk factors and longitudinal outcomes. In many institutions, the same transdisciplinary teams that collaborate in screening programmes have already implemented broader programmes for managing incidentally detected nodules, and locally track the same data as required for screening reimbursement.

Smoking cessation

Among the major opportunities of lung cancer screening is the provision of smoking cessation counselling to current smokers, and reinforcement of cessation in former smokers.⁹ Indeed, successful smoking cessation strategies, usually combining motivational interviewing and pharmacotherapy, are among the most beneficial derivatives of lung cancer screening.¹⁰ Considerable data have been collected on the most successful smoking cessation

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