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Should CMS Cover Lung Cancer Screening for the Fully Informed Patient?

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Lung cancer is the leading cause of cancer death¹ and an estimated 12,000 lung cancer deaths could potentially be averted each year in the United States through early detection with low-dose computed tomography (LDCT).² The Centers for Medicare & Medicaid Services is currently considering national coverage of lung cancer screening with LDCT for individuals at high risk of developing lung cancer based on their age and smoking history.³ The U.S. Preventive Services Task Force (USPSTF) recently updated its recommendation about screening for lung cancer to recommend annual screening with LDCT for adults aged 55–80 years who have a 30-pack-year smoking history and who currently smoke or have quit within the past 15 years (B recommendation, update published December 31, 2013).⁴ In making its recommendation, the USPSTF weighed many factors including the estimated 16% mortality reduction associated with screening and surgical resection⁵ and the high false positive rate associated with screening.⁶

Unlike new private insurance plans, coverage of preventive services with a grade of A or B by the USPSTF is not mandatory for Medicare. CMS is allowed to cover additional preventive services if it determines through the Medicare national coverage determinations process that the service is reasonable and necessary for prevention or early detection of illness, is recommended with an A or B grade by the USPSTF, and it meets certain other requirements.

MEDCAC Evaluation and Recommendations

On April 30, 2014, the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) met to consider the evidence regarding lung cancer screening with LDCT in asymptomatic adults with a history of significant smoking.³ MEDCAC supplements CMS' internal review process by providing what is hoped to be unbiased, expert advice on topics

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under review by Medicare. The committee voted low to intermediate confidence on the questions: “How confident are you that there is adequate evidence to determine if the benefits outweigh the harms of lung cancer screening with LDCT (CT acquisition variables set to reduce exposure to an average effective dose of 1.5 mSv) in the Medicare population?” and “How confident are you that the harms of lung cancer screening with LDCT (average effective dose of 1.5 mSv) if implemented in the Medicare population will be minimized?”

The committee’s concerns included the high false-positive rate of screening, the associated low positive predictive value, and the unknown cumulative risk of radiation exposure. The generalizability of the National Lung Screening Trial (NLST) protocol to the Medicare population and potential important variances in screening program implementation were also cited as concerns (e.g., safeguards to ensure minimal radiation exposure, “eligibility slippage” including not adhering to the 30-pack-year threshold, screening more frequently than annually, and raising the upper age limit for screening). Despite these issues, the MEDCAC vote was criticized by screening advocates, some physicians and professional medical organizations.

If CMS follows the MEDCAC recommendation and decides against national coverage for lung cancer screening, the Medicare population would have to rely on the independent coverage decisions of individual insurers, pay for the costs of screening, or both. Financial barriers would discourage many high-risk individuals from obtaining lung cancer screening even if they considered the risk/benefit profile to be favorable.

In supporting lung cancer screening, the USPSTF⁴ endorsed the fundamental principles of shared decision making. Should CMS provide national coverage for lung cancer screening with LDCT for the fully informed patient? In our opinion, the answer to this question is “yes.” Shared decision making could help address some, but not all, of the MEDCAC concerns by minimizing implementation variances and improving patient-physician communications about the risks and benefits of LDCT screening. Through a shared decision-making process patients are made aware of their options, given opportunities to deliberate with their physicians and others about the options, and make fully informed and values-based decisions. This will be particularly important in the elderly population because life expectancy and increased risk of harm from the consequences of screening and treatment should be part of the discussion. Frail elderly patients may not benefit from lung cancer screening in contrast to patients who are younger and healthier.

Informed Decisions

For patients to make fully informed decisions, they need a basic understanding of the available options. Understanding begins with an awareness that screening for lung cancer is a *decision* and that not screening is an acceptable choice. A fully informed patient is aware that lung cancer screening involves both potential benefits (e.g., reduced mortality from lung cancer) and potential harms (e.g., radiation exposure, false-positive results). Harms resulting from the screening cascade can include the physical and psychological effects of screening, diagnostic procedures, treatment, financial strain, and opportunity costs that result from

participating in screening.⁷ Forgoing screening may lead to a diagnosis of lung cancer at later stages, when treatments are often more frequent and toxic, and currently less effective. Although rarely addressed during the clinical encounter, a completely transparent discussion of out-of-pocket costs of screening, including an estimate and the potential range of these costs, should be provided to patients.⁸

Physicians play an essential role in providing a high quality, shared decision-making process. They should assess the patient's understanding of factual information related to lung cancer screening options and trade-offs. The deliberation process involves exploring the patient's values regarding the trade-offs and potential outcomes of the decision. Decision deferrals also should be supported. The discussion and the patient's decision should be documented in the medical record.

Toward Shared Decision Making

Patient decision aids are adjuncts to the clinical encounter that help physicians and patients to participate in decisions that involve weighing the tradeoffs between treatment or screening options. A recently updated Cochrane review included 115 randomized controlled trials of patient decision aids published through 2012 and concluded that the use of these tools improves patients' knowledge about options, reduces perceptions of feeling uninformed or unclear about their personal values, stimulates patients to take a more active role in decision making, and improves the accuracy of their risk perceptions.⁹ International standards for developing and adopting patient decision aids exist, and guidance has been offered for certification of aids based on the standards.¹⁰

It is not enough to simply give patients a decision aid. The physician needs to ensure each patient understands the information and makes time to talk with the patient in exploring values, work with the patient to form a preference, and develop a follow-through plan for the selected decision. In addition, current smokers should receive smoking cessation services before referral for lung cancer screening. For current smokers contemplating LDCT screening for lung cancer, nicotine addiction and tobacco use are critical issues and smoking cessation needs to be a top priority.

The USPSTF acknowledged the importance of shared decision making for lung cancer screening: "The decision to begin screening should be the result of a thorough discussion of the possible benefits, limitations, and known and uncertain harms."⁴ There is a pathway to achieving high quality discussions and CMS should offer national coverage for the fully informed patient who elects screening after completing the shared decision-making process with a health care provider. Detailed documentation of the shared-decision process could be a requirement for financial reimbursement. Such a strategy could help to address some of the concerns raised in the MEDCAC review. Other important issues such as assuring that there are safeguards to ensure minimal radiation exposure, that there is no "eligibility slippage," and that screening and diagnostic testing is done consistent with LDCT will need to be in place.

Early detection of lung cancer through the use of LDCT is an effective, evidence-based strategy for addressing a cancer that is almost uniformly fatal and highly morbid in the

absence of screening. Patient decision aids are a means to make lung cancer screening a more transparent, collaborative, standardized, comprehensive, and beneficial process.

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