

## **Lung Cancer Screening Clinical Practice Guideline Recommendations** **The Massachusetts Lung Cancer Screening Guideline Panel**

### **The Guideline Panel**

The Massachusetts Lung Cancer Screening Guideline Panel included 21 members (patients, primary care providers, lung cancer specialists, representatives of Massachusetts health care payers, and Department of Public Health staff) identified and selected by the research and facilitation teams established through a contract between the Patient Centered Outcomes Research Institute (PCORI) and the University of Massachusetts Medical School with the assistance of the staff of Massachusetts Health Quality Partners (MHQP).

The Panel met face to face on 3 occasions in 2013-2014 and engaged in other virtual meetings and discussions to assess the scientific evidence about screening for lung cancer with the low dose CT scans. The key recommendations of the Panel are summarized below.

### **Recommendation 1: Eligibility Criteria**

- A. Core age and smoking eligibility criteria (National Lung Screening Trial (NLST) criteria)
  - 1. Age 55 – 74 years
  - 2. 30 pack years of smoking or more
  - 3. Current smoker or quit no longer than 15 years before starting screening
  - 4. Discontinue screening at age 75. (Exception: Allow 3 annual screens for those *starting* at ages 73- 74)
- B. Individuals with one or more lung cancer risk factors other than smoking who *do not meet one or more of the NLST criteria* (A1-A3 above) may be offered screening only if their predicted risk of lung cancer in the next 6 years is  $\geq 0.95\%$  when calculated with the PLCO (M2012 version) risk calculator. This recommendation does not apply to individuals who have reached the maximum age for screening eligibility.
- C. Screening should not be offered when a provider familiar with the state of an individual's health believes the individual is not likely to benefit from screening because of current health status and/or life expectancy.

### **Recommendation 2: Frequency and Duration of Screening**

- A. Individuals meeting initial eligibility criteria should be offered screening annually as long as the individual meets the core age criteria as in Recommendation 1A. This recommendation should be reassessed within 2 years to determine whether multiple negative scans may be an indication of reduced lung cancer risk and a reason to discontinue or to modify the screening interval.
- B. For individuals who have been screened annually, screening may continue when the number of years since quitting becomes greater than 15. (Note: This recommendation should be reviewed no later than December, 2016 and periodically to compare the benefit and harms of the recommended approach compared to discontinuing screening when the number of years of abstinence is 15 or greater for those who have had one or more screens).

### **Recommendation 3: Education about Benefits and Harms of Screening**

Individuals who are offered LDCT lung cancer screening should:

- A. Receive education about the benefits and harms of screening, including
  1. The estimated probability of avoiding a lung cancer death due to screening given their estimated risk of lung cancer.
  2. The risk of overdiagnosis of lung cancer with attendant overtreatment and its morbidities.
  3. Morbidity and mortality from invasive diagnostic procedures that may follow a positive screening test, for individuals both with and without lung cancer.
  4. The possibility of incidental findings that may not be clinically significant, yet may lead to additional testing or interventions with harms of their own and with no benefit.
  5. The risk of developing a lung cancer due to radiation received from LDCT and follow-up diagnostic testing. Information about radiation risk should include experts' estimates that the risk of cancer from annual LDCT may be so low it cannot be measured and other experts' concern that cumulative radiation from repeated LDCT screens and follow-up testing has not been fully assessed and could cause harm.
- B. Have the opportunity to have questions, concerns, and uncertainties addressed in a shared decision making process.

### **Recommendation 4: Requirements for Sites Offering LDCT Lung Cancer**

All radiology sites that offer LDCT lung cancer screening must:

- A. Adhere to the American College of Radiology (ACR) standards specified in the "ACR-STR Practice Parameter for the Performance and Reporting of Lung Cancer Screening Thoracic Computed Tomography" with the exception of Section II (Indications and Contraindications). In any cases where the Massachusetts Guideline provides a recommendation different from one in the ACR Practice Parameter, the Massachusetts recommendation should be followed.
- B. Adopt and adhere to the American College of Radiology Lung-RADS protocol for the diagnosis and follow-up of nodules.
- C. Apply for and receive accreditation as an ACR Designated Lung Cancer Screening Center within one year of the issuance of this guideline.
- D. Employ radiologists reading LDCT scans who meet the physician requirements outlined in the ACR practice parameter for diagnostic CT.
- E. Confirm eligibility for screening before booking a screening appointment.
- F. Have a smoking cessation program that is fully integrated with the screening program. In practice this means that:
  1. All current smokers requesting to be screened receive a brief intervention some time before a date for screening is confirmed that includes the advice to quit smoking, and assessment of: a) current use of cigarettes, b) readiness to make a quit attempt, and c) interest in receiving additional information about quitting and/or smoking cessation counseling.
  2. Smokers ready to make a quit attempt in the near future or expressing an interest in learning more about how to quit successfully should receive a more intensive intervention by phone or in person by a trained smoking cessation specialist on or before the date of screening. The intervention should provide evidence-based counseling and recommendation of pharmacotherapy for cutting down and quitting, as well as assistance with obtaining further information, evidence-based counseling, support and access to pharmacotherapy as indicated.
  3. Screening sites should have a relationship with a local smoking cessation program and have a means for referring patients directly to a qualified smoking cessation counselor on site or

- nearby. Sites should provide information about the availability of evidence-based smoking cessation counseling to all patients and encourage patients to accept referral for counseling.
- G. Offer access to educational materials on the benefits and harms of LDCT scanning to screen for lung cancer to all patients (See Recommendation 3).
  - H. Offer an opportunity to engage with the designated staff person (e.g., a patient navigator) for a shared decision making discussion if a patient has not had such a discussion with another provider.
  - I. Track patients with positive findings on the LDCT to assure they are aware of recommendations for follow-up care and assist patients in identifying sources of qualified follow-up care as needed.
  - J. Maintain a database on all patients receiving an LDCT scan for lung cancer screening that includes results of the screening and follow-up testing, including a tissue diagnosis of lung nodules and masses that are biopsied and complications of invasive procedures. The database should conform to specifications to be defined by the Massachusetts Department of Public Health (DPH), and the data should be provided to the DPH upon their request. We recommend that screening sites and the DPH collaborate on the development of software to support uniform data collection and management by the sites. Sites should designate a staff person to manage all data collection.
  - K. Establish a quality assurance program that assesses adherence to all ACR standards (See A. above) and that includes review of the frequency of false positive and incidental scan findings, the frequency of invasive follow-up testing and, when possible, any morbidity and mortality associated with the testing and comparison of site performance on these measures to other sites in the state and to NLST outcomes. Adherence of patients to follow-up recommendations should be reviewed.

#### **Recommendation 5: Evaluation of Patients with Screen-Detected Nodules that Have an Indication for Invasive Diagnostic Testing**

- A. Decisions to recommend invasive diagnostic testing when LDCT follow-up protocols call for such testing and the performance of invasive diagnostic procedures should occur only at healthcare centers with established multidisciplinary teams that have experience in making these decisions and that have on staff physicians experienced in all invasive approaches to lung cancer diagnosis.
- B. The multidisciplinary teams should include a CT radiologist as defined in 4D above, a thoracic surgeon with experience in diagnosis and treatment of lung cancer, a pulmonologist experienced in advanced bronchoscopy procedures to diagnose and stage lung cancer, a pathologist, and an oncologist. The team should meet at least monthly to formulate diagnostic plans for patients with lung lesions suspicious for cancer.
- C. When communicating findings that include consideration of an invasive diagnostic test for lung cancer to the referring provider, screening sites should make it clear that the patient should be referred for care to an institution with a multidisciplinary team with the qualifications stated in item A above.

#### **Recommendation 6: Referral for Screening**

The Panel strongly recommends that whenever possible, a patient should be referred for lung cancer screening by his/her primary care provider or by another provider (e.g. pulmonologist, oncologist, thoracic surgeon) who has a relationship with the patient and is able to determine patient eligibility and to offer the patient education about lung cancer screening and shared decision making. This is important for both assuring optimal patient education about screening as well as assuring availability of a provider to inform patients of abnormal findings and to order and manage the results of recommended follow-up tests.

However, the Panel recognizes that a small number of patients may not have ready and convenient access to a provider who can make a referral and/or may desire to seek lung cancer screening without involving one of their providers. Screening patients who do not have a referral from an existing provider is optional for screening sites and requires approval from the Massachusetts Department of Public Health (DPH).

- A. Sites that choose to offer screening without a referral from a patient's existing provider and have DPH approval should take the following steps when dealing with patients without a referral:
  1. Explain to the patient the importance of engagement with a primary care or other established provider before undergoing screening.
  2. Encourage the patient to seek a referral from an existing provider or to seek to establish a relationship with an appropriate provider.
  3. Offer assistance in identifying an appropriate provider or in obtaining a referral if needed.
  4. If a patient continues to request screening without a referral from an existing provider, determine whether the cost of screening will be covered by the patient's insurance without a referral and, if it will not be covered, inform the patient that without the referral, he/she may have to pay for the screening out of pocket unless the cost is covered by the screening site.
  5. For patients who are otherwise eligible for screening and who continue to request scheduling without a referral from an existing provider, the Panel recommends that the patient be referred to a designated licensed independent professional (LIP) affiliated with the screening site who is involved in clinical patient care and who has agreed to assess patients prior to screening and to take responsibility for informing the patient of any abnormal screen findings and for ordering recommended follow-up tests. This LIP could be a mid-level practitioner who works with the screening program or any other qualified LIP who is not a radiologist. The LIP will have a face to face visit with the patient, confirm eligibility for LDCT screening, educate the patient on screening benefit and harms, offer shared decision making, review screening results with the patient, and order recommended follow-up studies when indicated.

**Recommendation 7: Department of Public Health Oversight**

- A. The Massachusetts Department of Public Health (DPH) should establish procedures for assuring that sites perform the recommended data collection and sharing of data with the DPH.
- B. DPH should require sites to use a data format compatible with the format being developed by NCI.
- C. The DPH should periodically evaluate adherence of screening sites to recommendations in these guidelines through review of the data collected by sites for quality assurance, site visits and other means deemed appropriate.