Developing a Low-dose CT Lung Cancer Screening Program

Lung cancer is the leading cause of death from cancer in both men and women, accounting for 27% of all cancer deaths in the US[1] and about 20% globally.[2] Tobacco use is the most common risk factor for lung cancer, with 70% of lung cancer deaths globally occurring in cigarette smokers. The five-year survival rate of lung cancer is 17.8%, worse than many other common cancers including breast (90.5%), prostate (99.6%), and colon (65.4%).[3]

Early detection and screening can reduce cancer mortality. The National Lung Cancer Screening Trial (NLST) demonstrated a 20% reduction in lung cancer mortality and cost effectiveness equivalent to other screening tests with low-dose CT. Based on this trial, in December 2013, the US Preventative Service Task Force (USPSTF) recommended annual CT screening for adults aged 55 to 80 years who have smoked at least 30 pack-years and are either current smokers or have quit within the past 15 years. In February 2015, the Centers for Medicare & Medicaid Services (CMS) announced a National Coverage Decision for low-dose CT lung cancer screening and a month later CMS approved the American College of Radiology (ACR) Lung Cancer Screening Registry for facilities to participate in as a requirement of coverage.

In August 2015, GE Healthcare became the first CT manufacturer with an indication for low-dose CT lung cancer screening.*

At the University of Michigan Health System, Ella A. Kazerooni, MD, MS, Chair of the ACR Committee on Lung Cancer Screening, and Professor of Radiology, Associate Chair for Clinical Affairs, and Director of Cardiothoracic Radiology at University of Michigan Health System, has been instrumental in setting up the health system's lung cancer screening program.

"The process of implementing a lung cancer screening program first involves identifying all the stakeholders across an institution or health system," Dr. Kazerooni says. "It's easy to think about who you need in radiology, but it also needs to include specialists, such as pulmonary medicine physicians who will likely manage the majority of participants with positive screening results, oncologists, and thoracic surgeons. Primary care providers are critically important to include because screening is fundamentally a public health tool."

In setting up the University of Michigan's Lung Cancer Screening Program, Dr. Kazerooni and her colleagues engaged the health system's population health program. The most important reason for taking this approach was to leverage available tools for improving the health of the local patient population and reaching out to providers across the health system.

"We needed help identifying who should be screened," she explains. "The old fashioned way is through grand rounds and meeting with physician groups one-on-one, which we do. However, we wanted to leverage tools such as our electronic health record (EHR) to make it easy for our primary care physicians to identify and refer appropriate patients."

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* See gehealthcare.com/lungscreening for a complete list of qualified GE CT scanners and indications for use. Not yet CE marked. For countries that require CE marking, this product cannot be placed on the market or put into service until made to comply with the Medical Device Directive requirements for CE marking. Not available for sale in all regions.

Along with pulmonary medicine, the population health group, and the health system's EHR leadership, Dr. Kazerooni and her colleagues developed a best practice alert (also known as a BPA) that will alert physicians and staff in primary care clinics if their patient should be considered for CT screening when certain conditions are met, specifically patient age and smoking history. With the BPA, clinic staff can order the CT examination, access a shared decision making aid, and refer the patient to the tobacco consultation service and/or a high-risk lung cancer clinic if they would like additional counseling before considering CT screening. Dr. Kazerooni adds that it is also important to use a BPA in clinics like cardiology, urology, and head-and-neck surgery, as these specialists often see health issues that are smoking-related.

As part of Dr. Kazerooni's role as Chair of ACR Committee on Lung Cancer Screening, she has helped develop several initiatives to bring quality and safe lung cancer screening practices to physicians groups. One of the first initiatives was a practice parameter for performance and interpretation of lung cancer screening CT scans.

"The practice parameter includes the technical specifications that need to be met to acquire a high-quality lung cancer CT screening examination," she explains. "One is low radiation dose that is adjusted to patient size. Second, the exam needs to cover the entire lung in a single breath hold. Third, a slice thickness no greater than 2.5 mm, and preferably 1 mm, should be used for sufficient resolution in order to both detect and characterize lung nodules."

These parameters generally translate to CT systems with 16 detector rows or more, Dr. Kazerooni says. Across the facilities in the University of Michigan Health System, all CT scanners are 64 detector rows and, therefore, low-dose lung cancer screening can be conducted on any system.

Interpreting lung screening studies

As Chair of the ACR Committee on Lung Cancer Screening, Dr. Kazerooni led the team that developed the Lung Imaging Reporting and Data System (Lung-RADS™), a standardized lung cancer screening CT reporting and management tool to "reduce confusion in lung cancer screening CT interpretations and facilitate outcome monitoring."

For reporting purposes, Lung-RADS divides nodules by size and density (solid, part-solid, and non-solid). Based on the nodule size and growth pattern over time, the screening exam is classified on a scale of 0 to 4. Categories 1 or 2 are considered negative screens and patients are recommended to continue annual screening. In categories 3 or 4, the nodules are larger and possibly growing, requiring an interval test before the next screening exam to better understand their biologic behavior and likelihood of being lung cancer. The most aggressive classification is 4B, for which a patient may next undergo a CT with contrast, PET/CT scan, or tissue

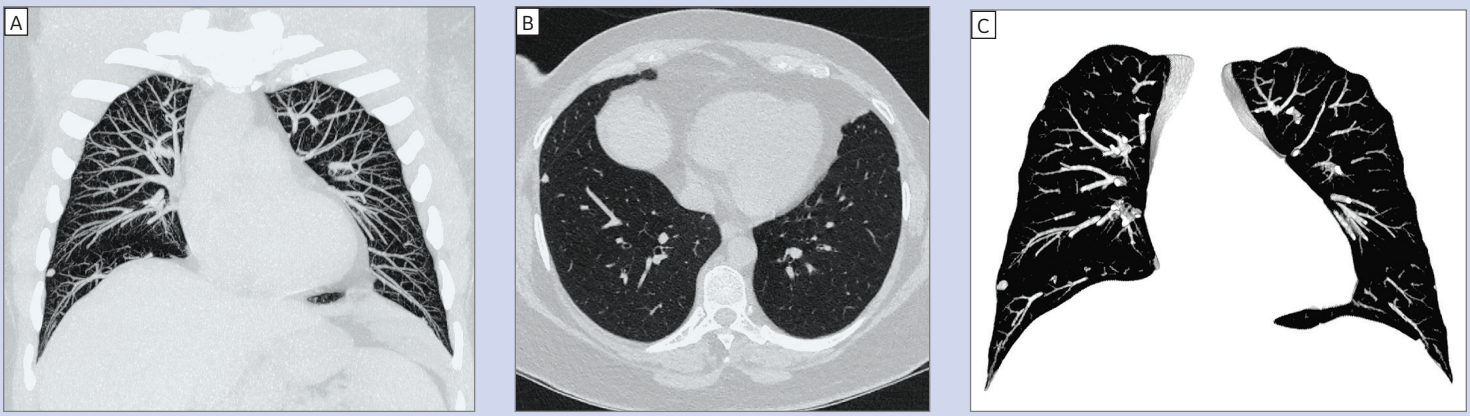

Figure 1. Example of a low-dose CT lung cancer screening exam. (A) 5 mm coronal MIP image; (B) 1.25 mm axial image; and (C) 20 mm volume rendered black and white lung image.

sampling by bronchoscopy or percutaneous biopsy—the decision should be based on the patient's individual risk for cancer and through multi-disciplinary discussion. This is where collaboration with pulmonary medicine physicians and thoracic surgeons is critical to tailor the next steps to what is best for the individual patient, Dr. Kazerooni says.

Although low-dose CT lung cancer screening is designed to detect cancer, Dr. Kazerooni points out it can also find many other medical conditions. Lung-RADS makes it very clear what findings require follow-up for possible lung cancer and also provides a mechanism for reporting other potentially significant findings. According to Dr. Kazerooni, these include an aortic aneurysm; a mediastinal, upper abdominal or lower neck mass; extensive coronary calcification; and emphysema. In Lung-RADS, there is a specific designation—code S—for these findings.

"The two most important other findings that I stress to our radiologists and others when I talk about lung cancer screening are emphysema and moderate or severe calcification," Dr. Kazerooni says. "With the notion that lung cancer screening is a public health tool, the three leading causes of death in the US today all sit in the thorax: cardiovascular disease, which we can see in coronary arterial calcification; lung cancer, the number-one cancer-killer in the US; and COPD and respiratory illness. Emphysema also increases the patient's risk of developing lung cancer. We can make a great impact in public health by finding these diseases and calling these out for special attention on chest CT scans."

Keys to success

Dr. Kazerooni has three core recommendations for other hospitals and health systems seeking to launch a low-dose CT lung cancer screening program: have a champion, be flexible, and have the proper infrastructure.

"I firmly believe the champion should be a radiologist, and that radiologist needs to demonstrate leadership towards public health and identify a clinical partner champion either from pulmonary medicine or primary care," she says. "This is a partnership between clinical colleagues—the radiologist who oversees the performance and interpretation of lung cancer screening CT and the referring and pulmonary medicine physicians who manage patients and the positive screens."

Health systems and hospitals also need to be flexible in bringing lung cancer screening to different specialties across clinics and offices. Dr. Kazerooni explains that as lung cancer screening moves from early adopters to population health it is critically important to enable widespread, mainstream screening.

"I don't think screening can be done only through a high-risk clinic," she adds. "If we only accept orders from a high-risk clinic, then we create a significant bottleneck to public screening."

Last, make the case to administration to provide the proper resources and infrastructure for a comprehensive program. With the CMS reporting requirement for reimbursement, sites need to collect information regarding the appropriateness of screening, radiation dose, the CT interpretation, and 12-month outcomes after a positive screen, including if a diagnosis of lung cancer was made and any tests performed to evaluate patients with a positive screen.

"It takes both human and technology resources to collect the data for the registry and ensure participants are not just identified, but managed," Dr. Kazerooni explains.

Dr. Kazerooni also urges radiology practices to use lung cancer CT screening as an opportunity to encourage abstinence in current smokers. Many participants who come for screening are current or former smokers trying to maintain smoking abstinence. Dr. Kazerooni believes that radiology practices can help participants who are ready to quit or reinforce that they should continue to not smoke.

"While we might think that participant consultation is something that primary care providers are responsible for, sometimes that readiness for the individual is when they come for their screening CT. So radiology practices can also provide information on how to quit smoking and available resources—it's just another teachable moment. Don't forget that we can play a role in smoking cessation. Smoking is the largest preventable cause of morbidity and mortality in the US today and radiologists can make a difference." ■

References

1. American Cancer Society. Cancer Facts and Figures, 2015.

2. World Health Organization. Cancer Fact Sheet, February 2015.

3. U.S. National Institutes of Health. National Cancer Institute. SEER Cancer Statistics Review, 1975-2011.