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## Lung Cancer Screening Success a Matter of Managing Risk

## By Tyler Smith

University of Colorado Hospital announced plans Nov. 13 to launch a lung cancer screening program with a straightforward aim: detect cancerous tumors earlier to keep patients alive longer.

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The announcement followed a decision by the Centers for Medicare and Medicaid Services (CMS) to begin coverage early next year of low-dose CT scans for eligible Medicare patients (see box). Some private insurers already provide the coverage, based on recommendations from the <u>U.S. Preventive Services</u> Task Force (USPSTF).



Medicare will begin covering low-dose CT lung images early next year for patients who meet eligibility criteria.

But gearing up to provide the screenings requires that UCH and other hospitals meet a host of requirements and that they decide how to allocate services cost-efficiently to patients with a wide range of cancer risk.

At UCH, thoracic radiologists will read and interpret the scans for eligible patients with a physician referral, said <a href="Peter Sachs">Peter Sachs</a>, MD, section chief of thoracic imaging for the Department of Radiology at the University of Colorado School of Medicine. The radiologist will then issue a report classifying the patient's likelihood of having cancer and provide the results to the patient and his or her physician.

Patients recommended for additional care are not obligated to receive it at UCH, Sachs noted. However, CMS will reimburse for the screenings only if hospitals have a multidisciplinary treatment program in place to give treatment options to patients, he said. Such a program is available at UCH through the <a href="Nodule Clinic">Nodule Clinic</a>, the Lung Cancer Clinic, and the Multidisciplinary Lung Cancer Program.

Reimbursement also requires that hospitals build and maintain a database to gather and track information on the screenings administered, interventions, follow-up care, and outcomes. Hospitals will submit the data to a registry maintained by the American College of Radiology as part of a long-term effort to assess the effects of the screening program. Kristen Petrillo, MSN, a nurse practitioner with the University of Colorado Cancer Center, will administer the hospital's database.

**Lung cancer on trial.** The foundation for the USPSTF recommendation is the National Lung Screening Trial, a randomized study of some 53,000 current or former 30-pack-year smokers (those who smoked one pack of cigarettes a day for 30 years or the equivalent thereof). One group received low-dose CT scans three times a year with follow-up at five years; the other received the same regimen of chest X-rays.

The trial results, published in August 2011 in the <u>New England</u> <u>Journal of Medicine</u>, showed that there were more lung cancer cases detected in the CT scan group, but fewer lung cancer-related deaths, presumably because the scans detected cancer earlier.

On the surface, the recommendation to screen people at high risk for lung cancer appears air-tight, said <u>Stephen Malkoski</u>, MD, PhD, with the CU School of Medicine's Division of Pulmonary Sciences and Critical Care Medicine. Malkoski also co-directs UCH's Nodule Clinic, where he and <u>Derek Linderman</u>, MD, diagnose lung spots identified by imaging studies.

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Lung cancer kills more people than breast, colon, prostate, and pancreatic cancer combined, Malkoski noted. It is particularly deadly if it is not detected early, when nodules are small and have not had a chance to spread to lymph nodes and other organs. The average five-year survival rate for patients with stage IV non-small cell lung cancer is just 7 percent at the University of Colorado Cancer Center. And that's considered exceptional — the national average is 1 percent, according to the American Cancer Society. Conversely, patients with various grades of stage I lung cancer have five-year survival rates ranging from 30 to 50 percent.

Screening for the disease is a statistical winner: It takes roughly 300 low-dose CT scans to save the life of one lung cancer patient, a far better average than for breast cancer screenings, which have long been fixtures of medical practice. The ratio falls to 1-to-160 for the 20 percent of patients at the highest five-year risk for lung cancer deaths. Malkoski added.

**Rating the risk.** But a more detailed analysis of the screening numbers shows that providing lung cancer screenings to a high percentage of the estimated 8.6 million patients eligible for the screenings will present operational challenges and hard policy decisions.

Malkoski noted that the 20 percent of patients at lowest risk for lung cancer will require nearly 5,300 screenings to save a single life. Moreover, the lower the risk, the greater the number of "false positive" screenings, he said. Without careful evaluation, that could mean additional imaging scans, with the attendant exposure to radiation, as well as biopsies and even surgical procedures for patients who don't have cancer. Malkoski anticipates a large increase in the number of referrals to the Nodule Clinic, which currently is open just one morning a week.

"We anticipate a significant increase in imaging volume and patient care," Sachs said, noting there are thousands of people in Colorado who meet the screening criteria. Starting in January, he added, the Epic electronic health record for University of Colorado Health hospitals will fire a best practice advisory for physicians whose patients meet the USPSTF screening criteria. That promises to funnel many individuals at various levels of risk through the system.

The advantage to screening those in the lowest-risk group is probably small, Sachs said, but for now, hospitals will have to

follow the USPSTF guidelines and wait to crunch the numbers on outcomes.

**Allocating resources.** "We have to validate whether or not screening the lowest-risk quintile is worth it," he said. "It's an iterative learning process." In addition, he said there are some people at high risk for lung cancer — those exposed to radon and asbestos, for example — who for now aren't eligible for the scans.

"We'll probably narrow the population or widen the criteria for screening as we go forward, based on other risk factors," Sachs said.

For Malkoski, the key to maximizing the benefit of lung cancer screening is identifying patients' risk and tailoring treatment appropriately. Those at highest risk for the disease should be referred for low-dose CT screening in the greatest numbers possible. More than half of the prevented deaths in the National Lung Screening Trial were among the 20 percent of patients in the highest risk group.



Peter Sachs, MD, section chief of thoracic imaging at the CU School of Medicine (left) and Stephen Malkoski, MD, PhD, with the Division of Pulmonary Sciences and Critical Care Medicine, see assessment of risk as the key to the success of the lung cancer screening program.

In the clinic, Malkoski uses a <u>risk calculator</u> that includes smoking history; clinical factors like body mass index; family history; and demographic details to assess a patient's probability for lung cancer in the next six years. Another calculator uses nodule size, type, number, and location to assess the risk of a lung cancer diagnosis in the next two to four years. He includes the risk calculations in the patient's medical notes.



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"We counsel patients in the clinic and give them the notes to help them make an informed decision on treatment options," he said. Careful risk assessment also helps to ensure that patients avoid unnecessary imaging and diagnostic procedures and surgeries, he said.

The greatest challenge, Malkoski concluded, is not in figuring out how to administer millions of additional lung cancer screenings, but rather in responding appropriately to the findings the screenings present.

"We should see a decrease in the number of advanced-stage cancers," he said. "We can save a huge number of lives in a cost-efficient way, but it has to be done correctly."

## Who Gets Screened?

Low-dose CT lung cancer screenings are open to patients referred by their physicians who meet the following criteria:

- » Current or former smokers who quit less than 15 years ago
- » Between the ages of 55 and 74
- » Smoking history of at least 30 pack-years (this means 1 pack a day for 30 years, 2 packs a day for 15 years, etc.)
- » No personal history of lung cancer