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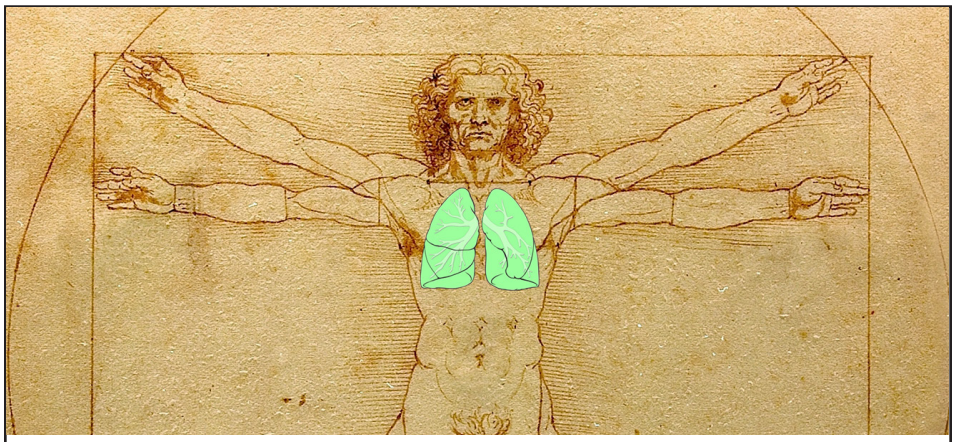

Does a B from USPSTF Guarantee Coverage? Lung Screening will Define Medicare Stance

By Paul Goldberg

The Centers for Medicare and Medicaid Services is facing the formidable challenge of deciding what kinds of patients should be screened for lung cancer.

The agency's Medicare Evidence Development & Coverage Advisory Committee will meet April 30 to decide how the positive findings of a large randomized trial and the recommendation the U.S. Preventive Services Task Force should be translated into policy.

The controversy over screening for lung cancer will demonstrate how scientific findings influence the standard of care in the new healthcare system. Under the Affordable Care Act, USPSTF grades translate into coverage mandates for private insurers.

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Conversation with The Cancer Letter

Kazerooni: The Case for Broad Coverage

The Cancer Letter asked Ella Kazerooni, a professor of radiology at the University of Michigan, chair of the American College of Radiology Committee on Lung Screening, and vice chair of the lung screening panel of the National Comprehensive Cancer Network, to lay out the rationale for a proposal for broad coverage for lung screening.

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In Brief

Ashworth Named Center Director at UCSF

ALAN ASHWORTH was appointed director of the **UCSF Helen Diller Family Comprehensive Cancer Center**, effective January 2015.

Ashworth is chief executive of the Institute of Cancer Research in London. Together with its partner hospital, the Royal Marsden NHS Foundation Trust, the ICR is one of the top rated cancer centers globally.

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CMS Committee Will Decide Which Risk Groups are Eligible

(Continued from page 1)

The U.S. healthcare system has historically encouraged rapid implementation of screening technologies. The government has been limited in its ability to put brakes on implementation of unproven screening technologies, and in situations where screening has been found to be not beneficial—or even harmful—doctors and the public resist efforts to limit access.

Now, Obamacare is lowering the barriers for coverage, but its ability to resist pressure from subspecialties and advocacy groups intent on broadening screening mandates remains untested.

The CMS advisory committee will have to decide which risk groups should be eligible for screening and whether data would continue to be collected after coverage is extended:

• Under one scenario, coverage could be extended only to individuals whose age and smoking history mimic those of participants of the National Lung Screening Trial, which found a reduction in long cancer mortality in the screened population. The care they would receive would have to be analogous to the care provided in NLST. This approach is reflected in the joint guideline issued by the American Society of Clinical Oncology, the American College of Chest Physicians, and the American Thoracic Society, and mirrored in the guidelines issued by the American Cancer Society that were part of the same evidence review.

• A second version of this approach—reflected in the formal request for CMS to launch a National Coverage Determination—would be to offer "coverage with evidence development." This would allow Medicare to continue to define the risk groups that stand to gain from screening. Such a policy would in effect narrow the availability of screening to clinics that are more technically sophisticated and preclude expansion of the screened cohorts.

• A third approach—advocated by a coalition which includes subspecialties that would perform the screening, workup and resulting treatment—would be to offer full coverage to the entire population that meets the NLST eligibility requirements. In addition, coverage with evidence development would be offered to broadened age and risk groups.

In addition to professional societies, this broadened approach is advocated by the Lung Cancer Alliance, a pro-screening group that has been closely connected with researcher Claudia Henschke and her International Early Lung Cancer Action Program (The Best of The Cancer Letter, Jan. 18, 2008, March 28, 2008).

"The medical and patient groups want CMS to provide full national coverage for high-risk patients as defined in the USPSTF recommendations and provide coverage with evidence for other high-risk patients not included in USPSTF recommendations using data collected through existing registries," the coalition of 40 groups said in a joint press release March 13.

National Comprehensive Cancer Network was part of the multi-society evidence review, along with ACS, ACCP and ASCO, but then adopted the broader set of guidelines.

"There probably is another population that is at equally high risk that should undergo screening," said Ella Kazerooni, professor of radiology at the University of Michigan and chair of the American College of Radiology Committee on Lung Screening.

"The only professional organization that has come out and recommended screening in that population is the National Comprehensive Cancer Network. And it's often referred to as NCCN Category 2[B]. And we would recommend coverage with evidence [development] for that population," said Kazerooni, who is also the vice chair of the NCCN guideline-making panel on lung screening.

"Their risk is slightly lower than the NLST enrollees, but it's still high. And if you look at the data out of NLST, even if you reduce the individual risk, the cost-effectiveness would still be there." Category 2B means that the recommendation is based on consensus

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that the intervention is appropriate.

A conversation with Kazerooni appears on page 1.

The population potentially targeted for screening has already been expanded.

The NLST population included individuals between ages 55 and 74 who had the smoking history of 30 pack-years. The USPSTF recommendation relied on modeling to extend this age to 80.

Critics say that the age and risk ranges in the NLST population is already considerable and exacerbated by reliance on modeling.

One major medical society, the American Academy of Family Physicians, an organization with 110,600 members, recently issued a clinical recommendation that opposes screening.

The results of NLST and the USPSTF grade notwithstanding, "the evidence is insufficient to recommend for or against screening for lung cancer with low-dose computed tomography in persons at high risk for lung cancer based on age and smoking history."

By way of comparison, the screening recommendation issued by ASCO and other organizations reads:

• "For smokers and former smokers ages 55 to 74 who have smoked for 30 pack-years or more and either continue to smoke or have quit within the past 15 years, ASCO suggests that annual screening with LDCT should be offered over both annual screening with chest radiograph or no screening, but only in settings that can deliver the comprehensive care provided to NLST participants.

• "For individuals who have accumulated fewer than 30 pack-years of smoking, are either younger than 55 or older than 74, or who quit smoking more than 15 years ago, as well as for individuals with severe comorbidities that would preclude potentially curative treatment and/or limit life expectancy, ASCO suggests that CT screening should not be performed."

Medicare has the authority—but not the obligation—to cover preventive services if the USPSTF gives them an A or a B recommendation.

Under the Affordable Care Act, services that get an A or a B from the task force cannot be subjected to copayments and deductibles in Medicare and private insurance. New A or B recommendations will be included in the HHS standards for private health plans.

Beyond NLST Findings and USPSTF Guideline

The 40 groups petitioning CMS are seeking to broaden the eligible population further to "other high risk patient populations where evidence is promising."

The groups propose to create screening standards analogous to those used for mammography.

The groups advocating for this approach include the Lung Cancer Alliance, National Comprehensive Cancer Network, American College of Radiology, the Society of Thoracic Surgeons, the American Association of Physicists in Medicine, the Academy of Radiology Research, American Association for Thoracic Surgery, the American Board of Radiology, the American Board of Radiology Foundation, American College of Surgeons' Commission on Cancer, American Roentgen Ray Society, American Society for Radiation Oncology, Association of University Radiologists, I-ELCAP, Prevent Cancer Foundation, Quantitative Imaging Biomarkers Alliance, Radiological Society of North America, Society of Chairs of Academic Radiology Departments, Society of Computed Body Tomography and Magnetic Resonance, and Society of Thoracic Radiology.

According to their joint position paper, *these expanded groups should include*:

1. The first category of individuals are those who may be slightly younger, with a lower pack-year smoking history but who have additional risk factors for lung cancer. Although the NLST provided excellent randomized trial evidence of benefit for a high risk group of patients, as a clinical trial the study limited its inclusion criteria to the risk factors of age and smoking history.

A wealth of pre-existing data has demonstrated several other clinically important risk factors for lung cancer that have not been addressed in the USPSTF guidelines, yet should be strongly considered for CED. An example of this high risk population is described in the attached National Comprehensive Cancer Network (NCCN) guideline and is also discussed in the I-ELCAP framework, protocol, and workup recommendations.

This population is often referred to as the NCCN category 2, and includes:

Individuals $\geq$ 50 years of age, with a $\geq$ 20 pack year history of smoking who have at least one additional risk factor for lung cancer (other than second-hand smoke), such as:

• Occupational exposure, specifically to agents that are identified as carcinogens targeting the lungs, including silica, cadmium, asbestos, arsenic, beryllium, chromium, diesel fumes, nickel, coal smoke, and soot,

• Cancer history, as there is an increased risk of developing new primary lung cancer among survivors of lung cancer, lymphomas, cancers of the head and neck, and smoking-related cancers,

• Documented high radon exposure,

• Family history of lung cancer,

• Disease history of Chronic Obstructive Pulmonary Disease (COPD) or pulmonary fibrosis.

2. The second category of individuals that should be included for coverage beyond the USPSTF guidelines, are 55-80 year olds who have a 30 pack-year or more history of smoking and who may have stopped smoking for more than 15 years.

Although these were not studied by the NLST, the risk of smoking-related cancers is predominantly related to total exposure and gradually decreases over time, meaning that these patients may remain at significant risk of lung cancer development.

Further, an arbitrary cutoff of 15 years would result in an implementation dilemma for patients who are covered for initiation of lung cancer screening, and who are then no longer covered for continued follow-up and screening after they have succeeded in smoking cessation for more than 15 years. This exclusion could even potentially lead to a paradox of incentives that 'encourages' a patient to restart smoking in order to maintain eligibility for lung cancer screening coverage.

What is the Standard?

The case of lung screening will illustrate the CMS standard for adopting a screening technology.

Does the demonstration of efficacy and a respectable B from USPSTF translate into unrestricted Medicare coverage?

Not necessarily.

According to a request for a CMS National Coverage Determination, submitted by Peter Bach, a pulmonologist and director of the Center for Health Policy and Outcomes at Memorial Sloan-Kettering Cancer Center, CT screening should first show effectiveness.

"It should be covered under Coverage with Evidence Development using a patient specific registry designed to ask several important unanswered questions about screening and its impact on beneficiaries that I detail in my request, and it should only be covered for beneficiaries who elect to receive the service after a data driven decision making discussion with their physician," wrote Bach, a MEDCAC member and a former CMS official.

"All the guidelines share a cautious tone regarding the harms of screening and the expertise that is necessary to perform screening in the least harmful and most beneficial way possible," Bach wrote. The guidelines from ASCO, ACCP and ATS note the importance of screening individuals only in settings that are able to deliver comprehensive care similar to that received by NLST participants.

"These screening recommendations came with several other caveats including the following: counseling should include a complete description of potential benefits and harms so the individual can decided whether to undergo LDCT screening; screening should be conducted in a center similar to those where the NLST was conducted, with multidisciplinary coordinated care and a comprehensive process for screening, image interpretation, management of findings, and evaluation and treatment of potential cancers. The USPSTF's draft recommendation statement and the AATS guidelines also acknowledge that limiting screening to settings with capabilities similar to those of the NLST sites could be beneficial."

Barnett Kramer, director of the NCI Division of Cancer Prevention, said it would be sensible to evaluate effectiveness of a screening modality after its efficacy has been determined.

"I think one is always on firmer ground if you first test a technology in a population in which it was proven to have had a net benefit and see if you maintain the net benefit in the community, and then if you do, then, of course you can start thinking about expanding that," Kramer said to The Cancer Letter. "As a matter of fact, we are talking internally about launching a lung cancer registry."

Caution in broadening the criteria before effectiveness is demonstrated in a wider community is a prudent approach, Kramer said.

"When you go beyond the actual empirical evidence from the definitive clinical trial, the further away you move from the actual evidence, the less certain you can be that the net benefits are maintained," he said.

The USPSTF recommendation, which relied on modeling to broaden the recommendation to include individuals of 80 and older is a "half-step" outside available data, Kramer said. "In the trial, you could be 74 years old, and three serial screens would already take you into your late seventies," he said. It was a very short step to go from 77 to 80. No one was being screened when they were 80, but there are very few—almost none—who were screened at 77."

The proposals to lower screening age to 50 for some individuals and lower the risks are extrapolations, which carry more uncertainty, Kramer said.

"The further you move away from empirical evidence, the more you have to rely on inference," he said. "This is often done because it has intuitive appeal that you predicate screening strategies not on observed balance of risks and benefits, but on underlying risk for the disease. That may or may not work. The alternative is first test it out to make sure that the balance of

benefits and harms out in the community—when it's disseminated—as was observed in the NLST and then start moving beyond that to see if you can maintain the same benefits and harms. But first do it in the population that mimics NLST."

Specialists have a tendency to advocate for more aggressive dissemination of screening technology, Kramer said.

"It is a good rule of thumb: there is a tendency for specialists who deal with the numerator—that is the people who have the disease—and advocacy groups that have a special disease interest to err on the side of doing more, just like generalists tend to be more conservative because they deal with the denominator." he said.

In an interview with The Cancer Letter, Kazerooni said the absence of ACS, ASCO and other major organizations on the letter submitted to CMS shouldn't be interpreted as disagreement with the aggressive pro-screening position.

"Many of these organizations, will not, by their own nature, co-sponsor other statements, unless they are writing them," Kazerooni said. "So I don't take it as a lack of support. I think they are very supportive of the comments that the ACR sent in in that consensus document."

Otis Brawley, chief medical and scientific officer of the American Cancer Society, said the difference between efficacy and effectiveness in lung cancer screening can be significant.

"There is clearly a place for lung cancer screening with LDCT," Brawley said to The Cancer Letter. "It is important to define that place.

"The NLST demonstrated efficacy. It showed that high quality LDCT of those at high risk combined with high quality diagnostics and treatment does prevent lung cancer deaths. It is important to remember that this well done study also showed that there were both benefits and harms.

"Unfortunately, many do not realize that there were documented harms. The trial demonstrated that the benefit to harm ratio was greater for those at the highest risk of lung cancer compared to those with lower risk but still qualifying for NLST.

"Said simply, when introduced into the real world, low quality screening can be very harmful and even high quality screening of those at lower risk may have an unfavorable benefit to risk ratio," Brawley said.

"It can be net harmful."

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Ella Kazerooni

Conversation with The Cancer Letter

From Clinical Trial to Public Policy: Kazerooni Discusses the NLST

(Continued from page 1)

ACR is a key player in an effort to get Medicare to offer unlimited coverage for screening of current and former smokers similar to those who were enrolled in the NCI National Lung Screening Trial as well as to offer screening to other groups believed to be at high-risk of developing lung cancer.

A request for a National Coverage Determination by CMS asks the agency to limit coverage to individuals whose age and smoking history mimics those of the NLST participants and to offer payment as "coverage with evidence development," in effect limiting availability of screening.

Kazerooni spoke with Paul Goldberg, editor and publisher of The Cancer Letter.

Paul Goldberg: *It's really quite fascinating to see how you translate the NLST into actual Medicare policy.*

Ella Kazerooni: It's a practical reality of lung cancer screening in a population.

PG: *Yeah, it's really fascinating. Are you pretty much the author of this approach?*

EK: I was one of the site PIs for the NLST study, and I chair the American College of Radiology's Committee on Lung Screening, which is trying to translate the scientific evidence into practice.

PG: *I didn't realize you were one of the investigators*

for NLST. I guess what I'm really wondering about is—well, there are two approaches on the table that I could see.

One is the [Peter] Bach approach, which is do coverage with evidence development, and the other is your approach that you're proposing, that is full coverage [within NLST population]—plus going outside NLST.

EK: My opinion is that NLST is a very well done trial.

It took eight years of patient enrollment and follow up. It's the largest randomized controlled trial of its type ever conducted in the United States, and it definitely showed that annual screening with low-dose CT reduces lung cancer mortality, which is what it was designed to try and prove.

And it proved that.

So to not cover lung cancer screening CT, I think, is unconscionable in the face of that evidence.

It's as cost-effective, if not more cost-effective than other things that are commonly screened for, today, including screening mammography for breast cancer, including screening for colon cancer.

And one of the reasons that it's more cost effective is because, unlike colon and breast cancer screening, which target the entire population of people of a certain age, lung cancer screening targets people of a certain age, but only high-risk smokers.

So the return for the money is greater, because you're targeting only a high-risk population instead of the whole population. So I believe it would be unconscionable to not cover this life-saving task for people at high risk for lung cancer.

PG: *What about the other part? I think that is a little bit more controversial.*

EK: The people who fell outside of the NLST, extending the age up a little bit, which is what the U.S. Preventative Services Task Force [recommended], I think would be appropriate for individuals who still have a good life expectancy.

Their risk of lung cancer doesn't go away, and the USPSTF showed through the modeling study that they conducted, that it would be of benefit.

The controversy is extending it to slightly younger people—to 50—to people with a lower smoking history, who may have additional risk factors.

We know there are other things that cause lung cancer other than smoking, although smoking causes the majority of cancers—about 85 percent of lung cancers are related to cigarette smoking, but about 15 percent are not, and they can be caused by things such as high-level of radon exposure.

They are associated with occupational exposure to a whole host of agents, and there is maybe even family risks factors, family history and genetics behind some lung cancers.

There probably is another population that is at equally high risk that should undergo screening.

The only professional organization that has come out and recommended screening in that population is the National Comprehensive Cancer Network. And it's often referred to as NCCN Category 2[B]. And we would recommend coverage with evidence [development] for that population.

Their risk is slightly lower than the NLST enrollees, but it's still high. And if you look at the data out of NLST, even if you reduce the individual risk, the cost-effectiveness would still be there.

I think they are worth covering, because they are still high-risk, more so than the general population, that the sensitivity analysis around the NLST data shows that you would do benefit for that population, but since there has been no randomized controlled trial, and we don't know with absolute certainty the way we do with a randomized controlled trial, I think that's the population that would best benefit from the coverage with evidence decision, so that data is systematically collected and can be reviewed in the future.

PG: *I guess one of the things that is going to be brought up is that this is a consensus guideline of organizations that represent the subspecialties that will be doing the screening.*

EK: That is not entirely true. The Lung Cancer Alliance is a patient advocacy group. They are not going to be doing the screening, they advocate for patients.

PG: *They are basically a [Claudia] Henschke group, I mean, they have always been.*

EK: I disagree with that. I really disagree with that statement. I am not on their board, but I'm very well aware of their activities—I support their advocacy, and I do not think they are an arm of I-ELCAP at all. I think they advocate for people who are at risk of lung cancer and they speak very articulately for people who have lung cancer and are at risk for lung cancer.

The Lung Cancer Alliance won't be doing the screening, they simply advocate for it. There are groups that signed onto the ACR consensus statement, such as The Fleischner Society.

The Fleischner Society is an international organization that represents not only radiologists, but pulmonary medicine physicians, thoracic surgeons, and thoracic pathologists. It is a multidisciplinary organization—they signed up to the statement.

The International Association for the Study of Lung Cancer is also a multidisciplinary organization with members from the same types of disciplines that I just stated to you. It's not a radiology organization. In fact, it's less of a radiology organization than it is a pulmonary medicine oncology organization. They signed onto the statement.

The National Comprehensive Cancer Network—there are very few radiologists who are involved in NCCN, and the NCCN guidelines relative to the number of oncologists, radiation oncologists and surgeons—they signed onto the statement.

And they are a relatively apolitical body, in general.

PG: *I don't see the American Cancer Society on the list. I don't see…*

EK: Yes, we contacted the American Cancer Society when we were putting our consensus statement together, and they sent in their own statement with very similar themes.

PG: *I don't think they are for going beyond the NLST, are they?*

EK: I think the American Cancer Society sent in their own organizational statement to Medicare.

PG: *ASCO is not on the list.*

EK: Similarly, ASCO sent in its own statement to Medicare. Many of these organizations, will not, by their own nature, co-sponsor other statements, unless they are writing them. So I don't take it as a lack of support. I think they are very supportive of the comments that the ACR sent in in that consensus document.

PG: *I guess the rationale for going beyond the NLST population is…*

EK: Is the risk. That NCCN Category 2 populations are still at high risk for lung cancer.

PG: *Is there anything we have not covered?*

EK: I guess other things people talk about are the false positives. Are the false positives too high? I would say that evidence has been collected through groups like NLST and ELCAP as well as some of the trials in Europe, is allowing us to raise the size of what we call a "positive screen," which means that there will be fewer positives screens, which means fewer downstream diagnostic tasks. This makes it even more cost effective.

Are you familiar with BI-RADS for breast cancer?

BI-RADS is a structured reporting scheme for mammograms, so when a patient has a mammogram, they get coded 0 through 5.

And the higher the code, the higher the chance of cancer, and more aggressive testing is done in terms of additional tests or biopsies. So we are developing the same sort of scheme for lung cancer screening—it's called LUNG-RADS—and it will do the same thing so that radiologists have a structured management reporting tool to follow, which we think will help people be more consistent in their interpretations and reporting.

BI-RADS has been out for 20 years and it's in its sixth edition and is used across the entire United States by breast imaging practices.

PG: *And I saw that mentioned, of course, in the document.*

EK: And we think the radiologists are calling for this. I just came from the Society of Thoracic Radiology annual meeting, it was this week in San Antonio, and spoke to this a little bit, and everywhere I go, radiologists come to me and say, "We need this, when is it coming up? We need it as soon as possible. We want to start using it."

PG: *One of the things that is kind of interesting is looking at Peter Bach's—well, Peter Bach is obviously playing a key role here, because it's his letter to CMS that seeks the coverage decision. But he's also making a point in his editorial [about] the USPSTF [recommendation] that, when you rely on modeling that much, you may open yourself to some problems.*

When you look kind of at the high end and the lower end of the risk scale, you are getting into very different populations. Is that a point that makes sense to you?

EK: Well, I would say that risk is not black-and-white. This is really a shade of grey from no risk to the highest possible risk.

So, NLST studied a high-risk population. It does not mean that's the only high-risk population. We know that there are many other risk factors for lung cancer, there are many other things—family history, exposures, radon, that increase a person's risk for lung cancer, and may increase it in equal amounts as the population that was studied by NLST.

It is unlikely that we will ever have a randomized, controlled trial for those people.

PG: *Right, which is the reason for coverage with evidence development. Yes, it is clear that there would not be such a thing as another randomized trial for those people.*

The other thing is the age. Medicare covers people over 65 with very, very, very few people who are under 65. Here you are talking about potentially pushing down to coverage of people who are 50.

What's the significance of doing that in this setting?

EK: I think one of the things that will be of interest for the MEDCAC panel: NLST reported 55 to 74, so roughly half of that population is under Medicare age,

and I think it will be very important to Medicare to see how does screening perform in the older half of the people who are screened relative to the younger half, and we believe it will perform equally well, if not better.

Extending it to an even younger population, the 50 will largely fall on non-Medicare payers, and again, I think, for them, they may want to in their national coverage decisions, do something similar to Medicare in terms of coverage with evidence.

PG: *You are really talking about Medicare then being really a part of deciding what commercial insurance coverage does.*

EK: Right, largely, many large third-party payers following Medicare decision-making.

So, we now, in this case, by January 2015, according to the Affordable Care Act, because USPSTF gave a B recommendation for the population, but third-party payers are going to be required to include this as a coverage benefit. That we know.

Could they put the NCCN Level 2 population into a different category and cover them with evidence decision as well? That's also possible. And if Medicare were to do that, that would increase the likelihood that others will do that as well.

PG: *It's sort of interesting how that is playing out in that way because Medicare suddenly becomes more of an arbiter, if I may, of what private insurance is going to be doing.*

EK: Well, it's kind of interesting, because it's a little different.

Because the third-party payers are going to be required to by next January, that's done already. So in this case, Medicare is following what third-party payers are already going to have to do.

And for Medicare to do something different than what the Affordable Care Act is requiring all other third-party payers to do, would be a strange dichotomy in the intent of the Affordable Care Act.

PG: *And that's the situation to which the Bach letter to CMS—the request for a coverage decision. Bach is asking them to do something commercial insurers won't have to do. Right?*

EK: Right. And that's kind of hard to get your arms around. If you are 55 to 65, you can get lung cancer screening, and then as soon as you hit 65, you can't?

PG: *Right, then you'd have to be in coverage with evidence development.*

EK: So you might be getting screened for two, three, four, five years and now, all of a sudden, you [can't get it]. It's doesn't make a lot of sense thinking about it from a patient population perspective.

It'll actually help for our patients to understand how the federal government can require third-party payers to do it until I hit 65, and after that, Medicare…

PG: *You drop off the cliff? I guess that 80 upper bound has to do with modeling, right?*

EK: A part of it is modeling; a part of it is common sense.

If you just look at the risk of those individuals for lung cancer, point from 74 to 75 to 76, it doesn't drop off. The caveat really is people getting screening need to be healthy enough to see the benefits of screening. So if you have severe coronary disease or malignancy with a poor life expectancy in five years, you probably shouldn't get mammography, and you probably shouldn't get lung cancer screening.

But if you are healthy and you have a five-, 10-, 20-year life expectancy, potentially, then you may benefit from screening.

I think one of the other things that keeps being brought up is this issue about radiation risk and concerns, and I would say that's really unfounded, and is generally used as a scare tactic.

People who are at the risk of getting lung cancer at that age, the likelihood of them ever developing and dying of a clinical significant cancer is really minuscule.

The greatest radiation risk is to children, teenagers and into young adulthood. But for individuals of this age, if you weigh the risks and the benefit, the benefit of CT are really on their side.

And I would say that the vendors have really worked to develop low-dose techniques, and kind of an outcry about what's going on with radiation exposure. Every vendor has developed lower-dose techniques.

I'm not concerned about radiation dose.

In Brief

Alan Ashworth Named Director Of UCSF Cancer Center

(Continued from page 1)

Peter Carroll will serve as interim director, effective April 1. He is associate dean of the UCSF School of Medicine, chair of the UCSF Department of Urology, and leader of the prostate cancer program at the UCSF cancer center.

Ashworth succeeds **Frank McCormick**, an internationally renowned molecular biologist who helped pave the way toward the development of targeted cancer therapies.

McCormick has taken on a leadership role as director of the RAS Project, a laboratory of the NCI that will focus on the mutated protein that plays a key role in a third of all cancers. He will also remain as a faculty member in the UCSF cancer center.

Ashworth was part of the team that discovered the BRCA2 gene in 1995. A decade later, Ashworth identified a way to exploit genetic weaknesses in cancer cells, including mutated BRCA2, leading to a new approach to cancer therapy. In 2008, he was elected as a Fellow of the Royal Society.

Ashworth, who has been with the ICR for 28 years, is a professor of molecular biology and leader of the gene function team in The Breakthrough Breast Cancer Research Centre at the ICR. The ICR has continued to be a world leader in isolating cancer-related genes and discovering new targeted drugs for personalized cancer treatment. Since 2005, the ICR has discovered 17 drug candidates and has taken seven drugs into clinical trials.

EDITH PEREZ was named the 2014 recipient of the **Claude Jacquillat Award**. She received the award during the 25th International Congress on Anticancer Treatment. Winners of this award are recognized for outstanding contributions to cancer patient care.

Perez is the deputy director at large of the Mayo Clinic Cancer Center, Serene M. and Frances C. Durling Professor of Medicine at the Mayo Clinic, and vice chair of the Alliance for Clinical Trials in Oncology. She is also chair of the Mayo Clinic Breast Cancer Translational Genomics Program and chair of the Breast Cancer Specialty Council. Her roles include positions within the American Association for Cancer Research, the American Society of Clinical Oncology, and NCI.

Perez has helped develop basic research studies to evaluate the role of genetic markers in the development and aggressiveness of breast cancer. She has authored more than 690 research articles in journals, books, and abstracts.

Jacquillat was the founder of the department of medical oncology of the Pitie Salpetriere Hospital.

CHAD ELLIS was named associate director of the **University of North Carolina Lineberger Comprehensive Cancer Center**, effective April 1.

Ellis will serve as the lead administrator for the center, overseeing the clinical protocol office, human resources, center finances, information technology as well as the physical infrastructure of the cancer center. He will also update the strategic plan for the University Cancer Research Fund, a $42 million state investment to support cancer research in North Carolina.

Previously, Ellis served as the deputy director of research affairs at the Yale Comprehensive Cancer Center. Ellis also served as a program director of the NCI Cancer Centers Program, overseeing a portfolio of 22 Comprehensive Cancer Support Grants awarded to NCI-designated cancer centers.

DEBASHISH TRIPATHY joined **MD Anderson Cancer Center** as breast medical oncology chair.

Tripathy is a professor of clinical medicine, co-leader of the Women's Cancer Program and holder of the Priscilla and Art Ulene Chair in Women's Cancer at the University of Southern California Norris Comprehensive Cancer Center.

He will replace Vicente Valero, who has served as interim chair since September 2012.

Tripathy joined UCSF's faculty as a clinical instructor in medicine in 1991. He was promoted to assistant clinical professor in 1993 and to associate clinical professor in 1997. In 2002, he joined the faculty at The University of Texas Southwestern Medical Center in Dallas as professor in internal medicine.

He also served as director of the Komen/UT Southwestern Breast Cancer Research Program. For the last five years, he has served as head of the Women's Cancer Section for the oncology division at the Keck School of Medicine.

His clinical research focuses on growth factor receptor pathway targeting and biomarkers that predict response or resistance to treatment. Specifically, he is working on understanding mechanisms of resistance to HER2-based therapy.

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SARAH THAYER was named the Merle M. Musselman Centennial Professor of Surgery and chief of surgical oncology at the **University of Nebraska Medical Center**. She was also named associate director for clinical affairs and physician-in-chief for the Fred & Pamela Buffett Cancer Center at UNMC.

Thayer comes to UNMC following a 13-year stint at Harvard Medical School and Massachusetts General Hospital. She has served as the W. Gerald Austen Scholar in Academic Surgery since 2002 and as director of the pancreatic cancer biology lab since 2008.

She is an active surgeon with a clinical and research focus on pancreatic cancer, and specializes in cancers of the breast and gastrointestinal system.

NCI announced the winners of the **2013 Cancer Center Clinical Investigator Team Leadership Awards**.

The two-year award for midlevel clinical investigators recognizes contributions to new therapies through collaborative team science, providing $50,000 in funding for those who lead cancer research programs and clinical trials at NCI-designated Cancer Centers. The funding is provided to the recipient's institution and can be applied toward the investigator's salary, fringe benefits, and associated facilities and administrative costs. Recipients are expected to devote 10 to 15 percent of their time to the activities associated with the award.

The 2013 awardees are:

• **Sikander Ailawadhi**, who was awarded the 2013 NCI CCITLA as an assistant professor of medicine at the University of Southern California Norris Cancer Center. Subsequently, he has joined the division of hematology and oncology at the Mayo Clinic as a senior associate consultant in order to pursue clinical, translational and outcomes-based research in B-cell malignancies, especially plasma cell disorders.

• **Jessica Altman**, associate professor of medicine in the division of hematology/oncology at Northwestern University. Altman's primary research efforts are based on increasing the understanding of the role of aberrant signal transduction pathways in the development of leukemias; defining molecular targets for the treatment of leukemias; and generating clinical trials based on such research work.

• **Lauren Byers**, assistant professor in the department of thoracic/head and neck medical oncology at MD Anderson Cancer Center. Her research focuses on the application of reverse phase protein array and other molecular profiling technologies for identifying novel therapeutic targets and predictive markers in lung and head and neck cancer. Her laboratory research helped identify that PARP-1 was overexpressed in small cell lung cancer cell lines and patient tumors.

• **Sarah Cooley**, assistant professor of medicine in the division of hematology, oncology and transplantation at the University of Minnesota. Her clinical time is spent is on the adult Blood and Marrow Transplant service, and her research focuses on immune-based therapies for cancer. She is the associate director of the Cancer Experimental Therapeutics Initiative, and the medical director of the Masonic Cancer Center's Oncology Medical Informatics and Services Core.

• **N. Lynn Henry**, assistant professor at the University of Michigan Medical School, and director of the Breast Cancer Survivorship Program a member of the Breast Oncology Program at the UM Comprehensive Cancer Center. Her research focus is on the predictors of response to and toxicity from breast cancer treatment, with a particular focus on the musculoskeletal side effects of aromatase inhibitors.

• **Cynthia Ma**, associate professor of medicine at the Washington University School of Medicine in Saint Louis. Ma has led multiple trials incorporating genomics in the treatment of resistant breast cancer, including the multi-center phase II trial of neratinib in HER2 mutated metastatic HER2 negative breast cancer and the ALLIANCE ALTERNATE trial, a neoadjuvant study testing a Ki67 based biomarker in patients with estrogen-receptor-positive breast cancer.

• **Mohammed Milhem**, deputy director for clinical cancer services at the Holden Comprehensive Cancer Center and leads the melanoma and sarcoma clinical research efforts. In the past year, these programs have accrued 72 subjects to therapeutic clinical trials and 312 subjects to a prospective tumor registry. He's helped coordinate the formation of the multidisciplinary groups for these two tumors and has integrated clinical trials from both industry and cooperative groups.

• **Timothy Showalter**, a radiation oncologist who specializes in male and female pelvic cancers and brachytherapy at the University of Virginia. He was an active member of the Radiation Therapy Oncology Group and will serve on the Genitourinary Cancers and Patient Centered Outcomes Research Committees of NRG Oncology.

• **Abby Siegel**, is co-chair of the Hepatobiliary

Subcommittee in SWOG, and is on the NCI Task Force for Hepatobiliary Malignancies. Siegel plans to develop clinical trials and education in SWOG, at Columbia University, and for potentially underserved groups in the NYC area. She is developing two SWOG hepatobiliary trials, and pairing junior faculty with senior SWOG investigators with similar interests. At Columbia, she is educating junior faculty on ethical conduction of clinical trials.

• **John Stewart IV**, of the Wake Forest Baptist Health Surgical Oncology Service. He focuses on the induction of cell death in gastrointestinal malignancies using oncolytic viruses, and his clinical interests are in general surgical oncology with a focus on melanoma, as well as breast, gastrointestinal, and peritoneal surface malignancies.

• **Eunice Wang**, of the Leukemia Section of Roswell Park Cancer Institute. Her research focuses on the role of angiogenesis and telomerase in hematological malignancies, screening anti-angiogenic and other biological agents for effects on clinically relevant human leukemia in vivo, and early stage clinical trials for acute leukemia. She also serves as associate program director of the joint Roswell Park/SUNY-UB Hematology-Oncology fellowship program.

LAURIE GLIMCHER and **THOMAS BURKE** were honored by **MD Anderson Cancer Center** for their work in promoting gender equality in medicine and research.

Glimcher, the Stephen and Suzanne Weiss Dean of Weill Cornell Medical College and provost for medical affairs of Cornell University since 2012, will receive the 2014 Margaret L. Kripke Legend Award.

Thomas Burke, executive vice president of the MD Anderson Cancer Network, will be honored with the President's Leadership Award for Advancing Women Faculty.

Glimcher, an immunologist, joined Weill Cornell from Harvard, where she was one of the first women professors awarded tenure. Her primary research interests are molecular pathways that regulate CD4T helper cell development and activation, work that has led to advancements in understanding immune function.

As president of the American Association of Immunologists, she founded the Primary Caregivers Technical Assistance Programs at the NIH. The program, which she also helped establish at Harvard, supports postdoctoral women scientists with child care responsibilities by providing additional funds for laboratory assistance. Under Glimcher, Weill Cornell opened an on-site child care center last year.

Burke joined the faculty of MD Anderson in 1988 and was appointed professor in 1998. In 2007, he was named executive vice president and physician-in-chief, an appointment he held through 2013 when he was named executive vice president of the MD Anderson Cancer Network.

As the physician in charge of clinical operations, Burke used his position to identify and promote women faculty to medical director positions. Burke is a practicing gynecologic oncology surgeon whose clinical and research work focuses on vulvar and endometrial cancers.

VENTANA MEDICAL SYSTEMS INC. has entered into a multi-year agreement with **Bayer Pharma AG** to develop companion diagnostics with a focus on immunohistochemistry, across Bayer's portfolio of targeted therapy projects.

This new agreement extends an already existing collaboration and focuses on the development of diagnostic tests for Bayer's biomarker targeted therapeutics from early discovery through commercialization.

Under the terms of the new agreement, Ventana, a member of the Roche Group, will create a team with resources exclusively assigned to Bayer projects. Financial terms of the agreement were not disclosed.

MD ANDERSON CANCER CENTER signed a three-year translational and clinical research agreement with **MedImmune** to develop anti-cancer immunotherapies through the center's Moon Shots Program. MedImmune is the global biologics research and development arm of **AstraZeneca**.

MD Anderson will evaluate several of MedImmune's immunotherapy molecules in a clinical setting, with the aim of identifying optimal combination therapies, assessing safety and efficacy, and developing biomarkers. The agreement is MD Anderson's third immunotherapy collaboration.

MD Anderson has invested $40 million in the platform, including philanthropic funds and a $10 million Established Investigator grant from the Cancer Prevention and Research Institute of Texas.