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### Title

JAMA Forum: Lung Cancer Screening and Evidence-Based Policy

### Permalink

<https://escholarship.org/uc/item/2qw3976g>

### Journal

JAMA, 313(1)

### ISSN

0098-7484

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### Publication Date

2015-01-06

### DOI

10.1001/jama.2014.16429

Peer reviewed

new patients to complete forms with questions about their personal and family medical history and marital status, but typically, the forms omit any questions about sexual orientation or gender identity, she says. "Right at the beginning, we discourage people from coming out."

Surveys have found that most physicians don't ask about patients' sexual orientation at their annual checkup, Eckstrand says. "Most providers don't know to ask the questions," Obedin-Maliver says. "Some providers feel these questions are inappropriate, invasive."

When they do ask, there often isn't a place for the answer in the electronic health record (EHR). In June 2013, the University of California, Davis, became the only academic medical center in the United States that has incorporated standard questions about sexual orientation and gender identity within patients' EHRs (Callahan EJ et al. *Acad Med*. doi:10.1097/ACM.0000000000000467 [published online August 26, 2014]).

"Specifically LGBT health centers around the country had been asking this question already, but no academic health center had," says psychologist Edward Callahan, PhD, associate dean for academic personnel and professor of family and community medicine at the University of California, Davis. "I've talked to a large number of places around the country that are making efforts to do it. We're the first, but we're not going to be alone for very long."

Still, not all physicians at his institution see the need to ask, says Callahan, a member of the AAMC's Group on Diversity and Inclusion, who at the top of his university home page notes that he welcomes LGBT patients (<http://bit.ly/1zR4UPN>). "We're still facing providers who think that it's not relevant—the doctor who says 'I treat all my patients exactly the same,'" he says. "The reality is it does matter a great deal. People have different needs, different risks, depending on who they are."

Although the AAMC guidelines are aimed at medical school students and

faculty, they could and should help inform training and continuing medical education for physicians, says Henry Ng, MD, president of GLMA (previously known as the Gay and Lesbian Medical Association). "I share with our trainees: people are held accountable for the care that they give—good, bad, or indifferent," says Ng, an assistant professor at Case Western Reserve University School of Medicine, which has offered an elective in LGBT health since 2008. Ng, an internist and pediatrician, helped develop and currently serves as director of the MetroHealth Pride Clinic, the first in Ohio to serve the health care needs of LGBT individuals.

The AAMC is already thinking about that, Nivet says. "What if we worked with some of the medical societies? What if we came up with modules that practicing physicians could use?"

Eckstrand doesn't want to stop there. "I hope this can be translated into other health professions," she says. "We are so proud of this work, but we think this is just the starting point." ■

## The JAMA Forum

# JAMA Forum: Lung Cancer Screening and Evidence-Based Policy

Andrew Bindman, MD

**M**any people have dreamed of a day when health policy might be based less on the political clout of special interest groups and more on research evidence. Evidence-based health policy could lead to more rational decision-making than typically occurs today. For this to work, however, we need a process to collect and consider all of the relevant evidence before formulating a policy.

The discussion surrounding the use of computed tomography (CT) scanning to screen for lung cancer is a case in point.

The Affordable Care Act (ACA) included a provision that requires private health insurers to cover, at no cost to their beneficiaries, "[e]vidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force (USPSTF)..." On its surface, this sounds like a logical approach for translating evidence

from research on preventive services into policy. The ACA removes patients' financial barriers to receiving the most efficacious preventive services; it also requires health insurers to invest in preventive care and creates a level playing field for them to do so. However, the evidence that the USPSTF finds relevant for its recommendations is not the only thing important to consider in establishing a policy on coverage for a potential preventive service.

Earlier this year, the USPSTF assigned a B rating to a recommendation for annual screening for lung cancer using low-dose CT scans for adults aged 55 to 80 years who have a 30 pack-year smoking history. The major evidence supporting this recommendation came from the National Lung Screening Trial, a randomized study that found a 20% reduction in mortality over a 4-year period among those receiving up to 3 annual screening CT examinations compared with



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those who received screening with chest radiographs. The B rating for the recommendation means that health insurers are required to cover the cost of the screening

chest CT scans at no cost to their eligible beneficiaries in 2015.

If the story ended here, we might have been naive enough to think that Congress had created a simple and successful way to ensure the intelligent translation of research evidence about preventive services into policy. However, Congress established a different process within the ACA for the Centers for Medicare & Medicaid Services (CMS) to expand Medicare's coverage of preventive services. The CMS can do so at no cost to beneficiaries based on the A and B level recommendations of the USPSTF, but unlike private insurers, it is not required to take this course of action. In the process of deciding whether to cover the cost of lung cancer screening, the CMS has revealed the limitations of what the USPSTF regards as meaningful evidence.

In its recommendations, the USPSTF places the greatest weight on randomized clinical trials. Randomized trials evaluate efficacy, telling us how well a preventive service works compared with alternatives in the idealized circumstances of a well-conducted trial, among narrowly defined populations of patients. Payers would be wise to make evidence of efficacy a basic requirement of a coverage decision but, as the discussion surrounding Medicare's potential coverage of CT lung cancer screening highlights, efficacy alone is insufficient as the basis of a coverage decision because it does not tell us how the service will perform in actual practice.

### Effectiveness vs Efficacy

Effectiveness, as opposed to efficacy, measures the benefits and harms of an intervention when it is applied in a real-world setting rather than the controlled environment of a study. For payers, including Medicare, the effectiveness of a preventive service, measured as the benefit-to-harm ratio in a population similar to its own, is more relevant than efficacy derived from a highly selective population within a controlled clinical trial.

There are many reasons to question whether the level of benefits vs harms for CT lung cancer screening experienced by Medicare beneficiaries (or enrollees of any health plan) would be as favorable as the level that the USPSTF estimated from its review of the clinical trials.

For one thing, physicians taking part in clinical trials tend to perform better than the average practicing physician. In broadening the use of lung cancer screening, one would expect that radiologists and surgeons in the community would be less successful in detecting and treating true positives than physicians participating in the clinical trials.

Second, although little attempt was made in the clinical trials to measure the harm associated with CT lung cancer screening, there are reasons to believe that it is significant and likely to become even greater if this screening test is made more broadly available. Nearly a quarter of study participants in the National Lung Cancer Study had a positive screening result and more than 96% of those were later determined to be a false-positive result, but we do not know the extent of the worry and suffering these individuals needlessly experienced.

We also do not know the out-of-pocket costs patients could expect related to follow-up studies to investigate these false-positive screening examinations, nor their excess cancer risk associated with exposure to the radiation used in the screening CT scans and any subsequent imaging studies. Expanding the use of lung cancer screening to an older population, as the USPSTF recommends, is also likely to lead to an increase in false-positive results related to noncancer related pulmonary lesions. In addition, there are no legally enforceable radiation dose standards for CT screening for lung cancer along the lines of what is in place for mammography screening. This will most likely result in the same sort of variation in radiation doses observed in the other diagnostic uses of CT, thereby paradoxically exposing those seeking preventive services to a higher risk of new cancers.

We should embrace a strategy of translating research evidence into health policy, but we need a process based on a robust understanding that goes beyond evidence collected in idealized circumstances. Before adopting a policy to pay for a new service in health care, we should expect not only an accurate estimate of the efficacy of intervention from randomized trials, but also its effectiveness and costs for relevant subgroups of payers and patients.

### Financial Incentives

We should also be mindful that once a preventive service is approved for payment, there is a strong financial incentive for physicians to broaden the population of eligible patients. This should be anticipated and evaluated for its effect on benefits, harms, and costs before establishing a policy to broadly cover the service. Furthermore, to make it more likely that the effectiveness of the scaled-up service will match what was observed in the tightly controlled clinical trials, we should consider additional requirements as a condition of covering the costs of efficacious preventive services, such as enforceable standards of radiation dose.

Stakeholders with substantial financial interests are aggressively lobbying CMS to approve coverage for lung cancer screening with CT. But CMS has been down this road before, most recently when it rejected coverage for CT colonography for a lack of evidence about its effectiveness in an elderly population. In that case, CMS signaled that it was holding the medical research community to a higher standard before adopting its evidence as policy.

Those who envision a day when health care policy is based on science should be heartened by CMS' deliberate approach in adopting new benefits for coverage. We hope that this approach can not only withstand the substantial pressure of stakeholders with financial interests in the outcome of the decision, but also become a model for how to intelligently translate research into policy. ■

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**Published online** October 15, 2014, at <http://newsatjama.jama.com/category/the-jama-forum/>.

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