

CISNET Tailors Screening

Risk modeling for lung cancer is about to get much more sophisticated. CISNET teams have been working with the data from the National Lung Screening Trial and other clinical trials and are likely to report their results in the next few months. Pamela McMahon, Ph.D., associate director of the Institute for Technology Assessment at Massachusetts General Hospital and principal investigator for CISNET's lung cancer group, said the group's goal is the same as that of the Liverpool Lung Project: "to make screening efficient by screening those at highest risk." But whereas Liverpool is a statistical model, CISNET simulates individual people.

"What we're doing is much more detailed regarding the natural history of the disease," she said. "Like 'The Sims' [a video game] without the graphics, we simulate a population over time. We can impose

screening or not, have people start or stop smoking. We're trying to figure out what questions to ask. What if we screened for more years? What if we screened people with a shorter smoking history or started screening at an earlier age?"

In addition to other questions, the CISNET modelers will look at the relationship between smoking behavior and screening. Although a false-positive screening test could scare people out of smoking, it's equally possible that others could take a negative test as a license to continue smoking. "We need to inform them that a negative screen doesn't mean they don't need to worry about smoking," said Levy.

Another important variable for the CISNET teams is what clinicians do to follow up a positive screening test. "If you can reduce the bad effects of a false positive," said McMahon, "that moves the threshold toward screening more people—you

could get more benefit for the same level of harm."

"Screening always involves trading off benefits to those at high risk and harms to those who won't get it," she explained. "We're looking at a huge population, most of whom won't have the cancer. There's a small risk overall, but it's unequally distributed. Some people will get a big benefit [screening finds cancer early, extending their life], but many will get a tiny harm [screening flags something that proves not to be cancer]."

Asked whether she saw risk-based screening as the wave of the future, McMahon hesitated. "I don't see a lot of that," she said. "I'd like to think we're getting closer, but there's a lot of pushback. When you say we're screening only those at a certain risk, people accuse you of rationing care. So it's not a foregone conclusion."

© Oxford University Press 2012. DOI:10.1093/jnci/djs631

Conflicting Clinical Guidelines

By Charlie Schmidt

When the U.S. Preventive Services Task Force (USPSTF) issued guidelines against prostate-specific antigen (PSA) screening last May, the American Urological Association responded with a scathing rebuttal: The move was outrageous, claimed the association, whose own guidelines take a far more favorable view of the PSA screen. Covered widely in the media, the volatile debate over PSA tests pitted one set of clinical practice guidelines against another. But that's hardly unusual. Recent decades have seen a surge in guidelines, now numbering up to 3,700, according to the Institute of Medicine (IOM)—and many give inconsistent or opposing recommendations on the same clinical topics. "It's a jungle out there," said David Ransohoff, M.D., a professor at the University of North Carolina School of Medicine in Chapel Hill. "This is a huge topic that goes to the heart of our profession. Anyone can make guidelines, and our

evidence-based medical system is coming under attack by special-interest groups."

Conflicts of Interest on the Chopping Block

Experts in medicine and health policy are trying to identify and root out conflicts of interest that might skew guideline recommendations. Those efforts are aided by a 2011 IOM report, *Clinical Practice Guidelines We Can Trust*, which created a standardized framework to ensure transparency and scientific credibility in guideline development. The American Cancer Society (ACS), for instance, which IOM singled out as a model for how not to create guidelines, has revised its own process to make them more transparent, with input from clinicians with no stake in the outcome. ACS now takes public comments into account before issuing final guidelines, said Otis Brawley, M.D., chief medical officer and

executive vice president. Brawley said this newer approach, a response to the IOM report and involving an extensive literature review guided chiefly by generalists, departs from the back-room discussions ACS previously relied on. "We've got to get away from this black-box methodology," he said. "Trustworthy guidelines need to be developed out in the open."

Brawley cites two conflict-of-interest categories as a concern: those based on financial interest, which are relatively easy to identify, and those with an "emotional" component, which tend to be more troubling. John Santa, M.D., director of the Health Ratings Center at *Consumer Reports*, agreed. "Specialists and academic researchers can be wedded to their idea or hypothesis about how something works, and it's very hard for them to accept that there could be an [alternative] explanation," he said.

Meanwhile, professional societies take pride in their guidelines and see them as a

vehicle for showcasing their expertise to the public, said Sheldon Greenfield, M.D., director of the Health Policy Research Institute at the University of California, Irvine. Trouble comes when clinicians, patients, insurance companies, and others have to sift through conflicting recommendations to reach a decision. Ransohoff said the IOM report successfully described how trustworthy guidelines should be developed.

But it also failed, he added, to provide tools to compare existing guidelines with respect to quality.

Greenfield, who chaired the IOM guideline committee, said the report was only a first step toward that broader goal. “A lot of empirical work needs to be done so that we can refine the specifications for making quality comparisons,” he said.

According to Greenfield, dramatic increases in the amounts of information coming out of medical research make guidelines increasingly necessary. “How are doctors supposed to keep up with it all? We need to proceed with standardizing care so we can reduce variation, improve quality, and decide what to cover from third-party reimbursement.”

Guidelines and Reimbursement

Still, the shift toward guidelines can be unsettling, particularly to those who see them as imposing on the doctor’s freedom of professional choice. Jerome Groopman, M.D., a professor at Harvard Medical School, articulated that view in his article “Health Care: Who Knows Best?” published by *The New Yorker* in 2010. Focusing his ire on the 2009 USPSTF recommendation against mammography among women aged 40–49 (which he disagrees with),

Groopman warned of policies that might deny reimbursement to clinicians who deviate from government-approved “best practices.”

Indeed, the Obama administration’s Affordable Care Act stipulates that insurers offer preventive benefits in line with USPSTF recommendations. (USPSTF is an independent body of experts within the

Agency for Healthcare Research and Quality.) Kenneth Lin, M.D., an assistant professor of family medicine at Georgetown University in Washington, D.C., worked for the agency and claims that the administration often pressured it to delay

recommendations that people might perceive as limiting access to care. That became an issue with respect to the task force’s mammography guidelines, Lin said.

But according to Brawley, insurance companies have said they will continue to cover mammography screening voluntarily in younger women, even though the task force guidelines recommend against it. Similarly, the Secretary of the Department of Health and Human Services responded to the PSA guidelines by directing Medicare to continue offering the test to older men. Consistent with their position on mammography, insurance companies will continue to cover PSA screening among younger men, Brawley said.

Meanwhile, government health care programs increasingly rely on guidelines as benchmarks for quality. Accountable Care Organizations, for instance, which the Affordable Care Act tasked to offer the population comprehensive health services, put guidelines into clinical practice, according to Mary Barton, M.D., vice president for performance measurement at the National Committee for

Quality Assurance in Washington, D.C. Similarly, the committee relies on guidelines to develop performance measures used to

accredit health care plans. “And Medicare relies on guidelines to figure out what they’re going to pay for,” added Ransohoff.



John Santa, M.D.

Therefore, pressure for more consistency, or “harmonization,” in guideline recommendations is mounting. “This is the next big step,” said Greenfield. What’s needed, he emphasized, is more willingness among guideline developers to compromise and to relinquish what they might see as an optimal approach for an alternative they can live with. “There are going to be winners and losers,” he said.

Santa added that a new program that *Consumer Reports* launched, called Choosing Wisely, reveals such willingness. Through the program, 18 professional societies are announcing five procedures they can recommend against to eliminate waste in the health care system. For instance, Santa said, the American Society of Clinical Oncology recommends that patients with solid tumors who fail all evidence-based cancer treatments and who are not eligible for clinical trials make the transition to palliative care. “To ASCO’s credit, they took the most difficult topic,” Santa said. “I can tell you from decades of practice that it’s not uncommon for cancer patients to be treated to the last minute of life.”

The key point, Ransohoff said, is that any organization’s guidelines advance a “triple aim” in health care: better outcomes, better patient experiences, and less cost. “We just have to anchor the guidelines in evidence,” he said. “They have to be trustworthy. This isn’t mystical stuff.”

© Oxford University Press 2012. DOI:10.1093/jnci/djs630

“Specialists and academic researchers can be wedded to their idea or hypothesis about how something works, and it’s very hard for them to accept that there could be an [alternative] explanation”