

99mTc-exametazime mammoscintigraphy (500 MBq) of a 60-year-old woman in whom a 35-mm breast tumor was found at mammography. Left, image showing tumor activity (arrow). Right, same image showing ROIs used when evaluating patients of the comparative study (group II). Tumor ROI (yellow) is surrounded by 4-pixel-wide background ROI (red).

In the Eye of the Storm

Don't expect the impact of the USPSTF's recommendations to disappear anytime soon.

●By Raina Keefer

lot can happen in eight months. In that time, the United States Preventive Services Task Force (USPSTF) released its recommendations for screening mammography, and perhaps more importantly, an estimated 126,490 women were diagnosed with breast cancer.¹

Many radiologists will come to know these patients as individuals rather than impersonal statistics. They will celebrate the successes, commiserate on the lows, and look for ways to ensure that, as physicians involved in clinical imaging, they discover other patients' cancers earlier. Screening mammography, the subject of the USPSTF's analysis, is one of the tools radiologists can use to detect cancers earlier, with documented evidence of value.

Since the guidelines were revised in November, the issue has been a hot topic. Fortunately for patients, Sen. Barbara Mikulski (D-Md.) and others helped pass an amendment in December 2009 to health-care reform legislation that ensures women in their 40s will continue to have access to mammograms. Still, some states, such as California, have dropped mammograms from their programs for women ages 40 to 49.

Debates have been held at institutions all over the country, including one at Howard University in Washington, D.C., in April. During this particular event, Jenny Luray, president of the Susan G. Komen for the Cure® Advocacy Alliance and senior vice president of government affairs for Susan G. Komen for the Cure, said, "Whole states are removing women [ages] 40 to 49 from their screening program because of these guidelines.2"





Marcia C. Javitt, M.D., FACR, believes that the legislation passed in December 2009 to ensure women have access to mammograms is a stop-gap measure. Who knows what the future holds?



Carol H. Lee, M.D., FACR, is worried that women and their physicians won't take the time to complete the USPSTF's specific recommendation that women in their 40s should discuss with their doctor whether they should have a mammogram.

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Patients are also more confused and unsure whether they should get a mammogram and at what age. One radiologist, Charles J. Weitz, M.D., from Munson Medical Center in Traverse City, Mich., has taken a proactive approach to educate both his patients and referring

physicians about the science behind the guidelines. (For tips about talking to your patients, see "How I Do It," on page 22.)

Evaluating Radiology's Response

Most of the radiology community has spent the last eight months vehemently defending the use of screening mammograms in women ages 40 to 49. As noted on the USPSTF website, "The decision to start regular, biennial screening mammography before the age of 50 years should be an individual one and take patient context into account, including the patient's values regarding specific benefits and harms.³"

In fact, radiologists are so adamant and passionate about their views that some believe "the overreaction of radiologists to this issue may be perceived as self-interested and self-serving by the public as well as by our clinical colleagues," as Leonard Berlin, M.D., FACR, and Ferris M. Hall, M.D., FACR, write in the May 2010 issue of *Radiology*. "They make the points that we've been too contentious in our backlash and have responded confrontationally to the point where it may hurt us," says Marcia C. Javitt, M.D., FACR, *AJR* section editor for women's imaging, and section head of Body MRI and Genitourinary Radiology at Walter Reed Army Medical Center in Washington, D.C. "They thought it was going to appear as if we were just preserving our turf," she adds.

"I think their points aren't valid because these guidelines should be free of political and cost considerations, Javitt notes about this important debate. "Then again, there's a disconnect between the medical community and radiologists. They think we're out here all by ourselves talking about a disaster and that most of the rest of the world doesn't agree with us."

However, many do agree with Javitt — patients in particular. For example, a March 2010 article⁵ in *RadiologyToday* notes that many patients have been "appalled by the new suggested guidelines." Carl J. D'Orsi, M.D., FACR, director of breast imaging research at Emory University Hospital in Atlanta, comments, "It appears our patients are smarter than the ones who put out the recommendations."

Decrease in Mammograms

Even though the guidelines suggest that women in their 40s speak to their doctors to determine whether a mammogram is appropriate, Carol H. Lee, M.D., FACR, from Memorial Sloan Kettering Cancer Center in New York, believes that such a conversation is highly unlikely. "Women in their 40s are by and large healthy, with families, jobs, and responsibilities," she says. "How many will make an effort to talk about the risks and benefits of screening mammography? The average physician visit is seven minutes — when are you going to have the time to have that discussion?"

Lee's previous practice had a mobile unit that went out to health centers and offered free mammograms. Those patients who participated would receive a notice the next year from the health center informing them of upcoming dates when the van would be in their area. "So for those women who depend on these free mammograms and happen to be in their 40s, who do they call to have a discussion?" Lee asks.

"That's what I see as an unfortunate result of these recommendations," she says. "People who are disinclined toward mammograms are going to say, 'I knew all along that I didn't need this.' After years of trying to get the word out with breast cancer awareness month and stressing the importance of an annual mammogram, now we've turned the clock back."

In April, Lee attended the National Conference on Breast CancerSM (NCBCSM), which is co-sponsored by the ACR, and says that during one of the sessions, an informal poll surprised her. "They asked attendees for a show of hands for how many have seen a decline in screening volume, and a fair number of people

The Latest on Breast Imaging

You can stay up-to-date on future effects of the USPSTF's recommendations — turn to the AJR and the JACR for new, original research in mammography and analysis of any changes in mammogram coverage. For example, check out the recent JACR article (http://bit.ly/d0L0Gw) by Daniel B. Kopans, M.D., "The Recent U.S. Preventive Services Task Force Guidelines Are Not Supported by the Scientific Evidence and Should Be Rescinded." The AJR often features a section just for women's imaging, so you don't have to search for the content you want.

You can help educate your patients, too, on changes in breast imaging and general radiology. A new patient newsletter, The Scan, offered by the ACR, is downloadable and is an ideal publication for your waiting room. You can find the newsletter at www.acr.org/thescan.

The "In the News" section on the ARRS' WomensImagingOnline website is also a great place to find relevant news in women's imaging. ARRS staff searches the top news around the country in women's imaging and brings it straight to the site. Visit today at http:// womensimagingonline.arrs.org.

raised their hands," she says. She acknowledges that there could be a number of reasons for that — bad weather in parts of the country or the poor economy, which means many people don't have health insurance, but it was interesting to see, she says.

During the NCBC. participants would likely have also discussed another aspect of the panel's recommendations: the suggestion that clinicians should not teach women how to perform breast self-examinations. "We lack a body of evidence to

determine the efficacy of breast self-examination, and though there's nothing proving that it's definitely effective, there's also nothing saying that it's not," says Javitt.

Bigger Than Mammography

"I think we have a huge problem here that's bigger than mammography," says Javitt. "This problem deals with the process and procedure being followed. The process used to generate these recommendations was devoid of input from clinical experts and completed behind closed doors. Also, findings were submitted to Congress without review.

Further, according to an American College of Radiology press release,6 "the task force made its recommendations without allowing for public input or involving anyone with expertise in breast-cancer detection and diagnosis. Rejecting both randomized, controlled trials and already-existing modeling studies, [the task force] instead commissioned its own modeling study and made recommendations in reliance on this study before the study had ever been published, made public, or held to critical peer review."

"This will happen again, not necessarily in screening mammography but in other areas of medicine, like diabetes, glaucoma, or prostate cancer," Javitt adds. "In fact, it's already happened for glaucoma screening, and it's not the first or the last time things will be done in this manner." Javitt believes that the way the process is managed needs to be changed, if only by installing a point of time for review and debate. "You can't railroad the recommendations straight through to Congress with no access for the rest of us to discuss."

Interestingly, the USPSTF's website (www.ahrq.gov/clinic/ uspstfix.htm) appears to offer an "Opportunity for Public Comment" option but only for certain subject areas.

After the task force's recommendations were published in the Annals of Internal Medicine, many readers sent letters to the editor stating their opinions and asking questions. Members of the USPSTF addressed some of their queries in "Comments and Response on the USPSTF Recommendation on Screening for Breast Cancer," published in the online Annals of Internal Medicine in February.

In the February article, USPSTF Chair Bruce N. Calonge, M.D., M.P.H., chief medical officer and state epidemiologist for the Colorado Department of Public Health and Environment, Denver, and Diana Pettiti, M.D., M.P.H., from the USPSTF, responded to comments from several medical professionals,

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clarifying the panel's recommendations and process. Calonge and Pettiti state, "The attention attracted by this recommendation has given the USPSTF an opportunity to examine its processes and messages. Although the language of the recommendation was intended for primary care clinicians, we recognize that it was poorly communicated to the broader health-care community and public. Despite this, we reaffirm our finding that periodic mammography starting at ages 40 to 49 provides small net health benefit compared with starting at age 50."

One commenter who sent in a letter to the editor was convinced that the panel came to its decision in part by wanting to reduce costs and that it also took into account the additional expense of false-positives and related consequences. However, Calonge and Pettiti write, "The USPSTF has repeatedly rejected calls to use cost-effectiveness analyses in its recommendations and did not use them for this recommendation. The model used by the USPSTF was not a cost model, and the analysis was not a cost-effectiveness analysis in disguise. The USPSTF used falsepositive mammograms in the same way that colonoscopy was used as a counter for screening-associated risk in the decision analysis that supported the recommendation on screening for colorectal cancer.6"



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'Could Have Been a Positive Experience'

Although insurance payments for mammograms haven't really changed since the recommendations, nor has CMS changed its reimbursement process for mammograms, an unpredictable future still looms. "Even though the brakes have been applied to this by virtue of the legislation passed in December (H.R. 3590)," says Javitt, "there is the potential for these guidelines to be used to decrease reimbursement, and if there should be changes in Medicare coverage, private insurers may follow."

Further, as poorly communicated as the guidelines were, the process could have been a positive experience, says Javitt. "If the process were formulated differently, I think there could have been the potential for the USPSTF to help us navigate the very dangerous waters of health-care economics and managed care. It could help us not only to manage care but also to manage cost because, really, we haven't done that so well," she notes.

"If the panel uses a discovery process that is comprehensive and well-informed, it could make scientific decisions that save lives, could help govern cost containment, and incorporate recommendations that could drive health-care reform. If the panel doesn't use the data available in the right way — by looking at strength of evidence and quality of data — they've failed," Javitt says.

One of the big issues many have with the panel is that it didn't include breast care or imaging experts. So what's the ideal makeup of a group reviewing screening mammography? "I would include well-respected breast imaging experts, oncologists with breast imaging experience, primary care physicians who deal with breast imaging, and radiation therapists," Javitt recommends.

"The other groups that need to be involved in this are experts on outcomes — researchers who are able to interpret the data we have and know how to do a multiparametric assessment of objective evidence. Lastly, you need experts in public health who understand methods used and can assess methodology — in many ways, these are the translators, the people who can give us language of the available data and see what power they have and whether they are applicable."

Debate Rages On

Regrettably, you can't rewrite the past, and the panel's recommendations will continue to reverberate for a long time to come. "I think [the effects] will be ongoing," says Lee. "People are just very interested in it."

What about the next generation of radiologists and oncologists? How will they view or be taught about this controversial issue? "Their views are sure to be influenced by the views of those doing the teaching," says Javitt. "Since the adverse outcome of the USPSTF on screening-mammography

reimbursement is curtailed, it is unlikely to change teaching for the time being. Once the purse strings are tightened, those teaching will follow the money." For example, if CMS were to restrict mammogram coverage for women 50 and above, that may be how radiology of the future is taught.

Since the guidelines were released, the media have reported on the fervor from both the medical community and patients. The debate has even sparked comparisons between international breast-cancer screening practices, such as the United Kingdom's National Health Service Cancer Screening Programmes, which recommend women receive mammograms at age 50 and above.

More research is being done, and to add to the confusion, an MSNBC.com April 7, 2010 article⁸ notes that a "team of Danish scientists published a study showing that breast-cancer screening programs of the type run by health services in Europe, the United States, and other rich nations, do nothing to reduce death rates from [breast cancer]." Just a week later, the piece says, a British team published a study "showing a 'substantial and significant reduction in breast-cancer deaths' due to screening."

Debate about the practice of screening mammograms has been going on for a number of years, yet it's easy to find evidence to sustain the point of views of both mammography supporters and those unsure of its effectiveness. Regardless, as Javitt and Lee explain, breast-cancer awareness has come a long way, and to turn back now, is unconscionable. "The task force and those who agree with the recommendations say that we're basing our decisions on emotions rather than science," says Lee, "but even if you accept the numbers the task force put out, if you weigh the risks versus the benefits, [screening mammography] still makes sense."

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