

# Confused about mammography guidelines? 7 questions answered

Solution Breast cancer screening recommendations issued by the US Preventive Services Task Force succeeded—in clouding what's best, for whom. But the air is clearing and answers have emerged.

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ome clinicians were reconsidering the need for an annual mammogram even before the US Preventive Services Task Force (USPSTF) issued new guidelines late last year.

Andrew M. Kaunitz, MD, is one of those clinicians. In an editorial in the December issue of OBG MANAGEMENT, he was bold enough to declare: "My plan is to be more acquiescent when a woman says 'No' to an annual mammogram."<sup>2</sup>

Among the evidence he cited to justify that acquiescence was a recent article in the *Journal of the American Medical Association* that expressed concern about the high number of early cancers—including ductal carcinoma in situ—that are detected by mammography and treated even though many are unlikely to progress or ever become clinically significant.<sup>3</sup> This phenomenon—termed "overdiagnosis"—is one of the risks of breast cancer screening.

Dr. Kaunitz is professor and associate chairman of obstetrics and gynecology at the University of Florida College of Medicine–Jacksonville. He also serves on the OBG MANAGEMENT Board of Editors.

Although the USPSTF is the only official body to revise its recommendations on breast cancer screening so far, more changes seem likely. This article aims to sift through the static on the airwaves of late and offer concrete recommendations for practice. In the process, it addresses seven questions:

- How did USPSTF guidelines change?
- Why did they change?
- Why did the changes attract so much attention?
- What is ACOG's position?
- What do thought leaders make of the new guidelines?

Janelle Yates
Senior Editor

For more on the controversy surrounding USPSTF guidelines, and a retort, see the Editorial on page 8.

To see a foreshadowing of the guidelines, read the Editorial in the December 2009 issue, available at www.obgmanagement.com

And for a critique of new research on how the clinical breast exam boosts screening mammography, see Examining the Evidence in the December 2009 issue, available at www.obgmanagement.com

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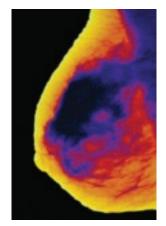
- Are the USPSTF recommendations likely to affect insurance coverage for mammography?
- What should you tell your patients about breast cancer screening?

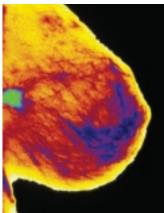
## How did USPSTF guidelines change?

In an article published November 16, the USPSTF made a number of revisions to earlier breast cancer screening guidelines for women at average risk of the disease:

- Routine screening mammography is no longer recommended in women 40 to 49 years old. Rather, the decision about when to begin regular screening should be individualized and should "take into account patient context, including the patient's values regarding specific benefits and harms" (Grade C recommendation).
- Screening mammography in women 50 to 74 years old should be biennial rather than annual (Grade B recommendation).
- Breast self-examination (BSE) is not recommended for any age group (Grade D recommendation).

The USPSTF found insufficient evidence





Approximately 39 million women undergo mammography each year in the United States, costing the health-care system more than \$5 billion.

to make a recommendation about screening mammography for women 75 years and older, about clinical breast examination (CBE) in women 40 years and older, and about digital mammography or magnetic resonance imaging (MRI) versus film mammography (I statements).<sup>1</sup>

## Why did the USPSTF guidelines change?

The changes were based on new data and analysis in the following areas:

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## CME/CE Webcasts and E-newsletters



from the American Society for Reproductive Medicine and its journal, Sexuality, Reproduction & Menopause



- E-NEWSLETTER 1. Issues in postmenopausal hormone therapy: Counseling patients about bioidentical hormone preparations Nanette F. Santoro, MD
  - Supported by an independent educational grant from Solvay Pharmaceuticals, Inc.
- E-NEWSLETTER 2. Issues in postmenopausal hormone therapy: Depression, endometrial health, and discontinuation James H. Liu, MD Veronica A. Ravnikar, MD, FACOG Nanette F. Santoro, MD

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- Supported by an independent educational grant from Merck & Co., Inc.



#### Among professional organizations, a resounding chorus of disagreement

fter publication of the new US Preventive Services Task Force (USPSTF) breast cancer screening guidelines late last year, it was only a matter of hours before official bodies and professional organizations began to weigh in on the changes, and the verdict was unanimous—disagreement. Among those chiming in were the American Cancer Society (ACS), the American College of Obstetricians and Gynecologists (ACOG), the American College of Radiology, the American Society of Breast Surgeons, the Society for Breast Imaging (SBI), and Susan G. Komen for the Cure, among others. Here are excerpts from their statements.

#### **American Cancer Society**

The ACS immediately refuted the USPSTF recommendations:

The American Cancer Society continues to recommend annual screening using mammography and clinical breast examination for all women beginning at age 40. Our experts make this recommendation having reviewed virtually all the same data reviewed by the USPSTF, but also additional data that the USPSTF did not consider....[T]he American Cancer Society's medical staff and volunteer experts overwhelmingly believe the benefits of screening women aged 40 to 49 outweigh its limitations.<sup>7</sup>

#### **ACOG**

The College reaffirmed its support for screening mammography every 1 to 2 years in women 40 to 49 years old and every year for women 50 and older, as well as breast self-examination for women of all ages:

At this time, The American College of Obstetricians and Gynecologists recommends that Fellows continue to follow current College guidelines for breast cancer screening. Evaluation of the new USPSTF recommendations is under way. Should the College update its guidelines in the future, Fellows would be alerted and such revised guidelines would be published in *Obstetrics & Gynecology*.<sup>5</sup>

#### **American College of Radiology**

The College minced no words in opposing the changes:

If cost-cutting US Preventive Services Task Force (USPSTF) mammography recommendations are adopted as policy, two decades of decline in breast cancer mortality could be reversed and countless American women may die needlessly from breast cancer each year.

These new recommendations seem to reflect a conscious decision to ration care. If Medicare and

- Mortality among women 40 to 49 years old. Although mammography screening reduces breast cancer mortality by 15% in this age group, the USPSTF concluded that "there is moderate certainty that the net benefit is small" in this population.<sup>1,4</sup>
- The effectiveness of BSE in decreasing breast cancer mortality among women of any age. Studies of BSE published since 2002 found no significant differences in breast cancer mortality between women who perform BSE and those who don't.<sup>4</sup>
- The magnitude of harms of screening with mammography. Mammography screening in women 40 to 49 years old involves a significant risk of harms. Although the USPSTF observed that the benefits of mammography in women 40

to 49 years old appear to be equivalent to the benefits of mammography among women 50 to 59 years old, it concluded that the harms outweigh benefits in the younger women.

Harms cited by the USPSTF include:

- · radiation exposure
- pain during the procedure
- · anxiety and distress
- an increased rate of false-positive results
- greater need for additional imaging and biopsies.<sup>4</sup>

The USPSTF conceded that the radiation exposure from a mammogram is minimal, but questioned whether cumulative exposure in young women might be problematic. It also noted that "many women experience pain during the procedure (range, 1% to

private insurers adopt these incredibly flawed USP-STF recommendations as a rationale for refusing women coverage of these life-saving exams, it could have deadly effects for American women," said Carol H. Lee, MD, chair of the American College of Radiology Breast Imaging Commission.<sup>8</sup>

#### **American Society of Breast Surgeons**

The organization released a statement describing its position as "strongly opposed" to the USPSTF recommendations:

We believe there is sufficient data to support annual mammography screening for women age 40 and older. We also believe the breast cancer survival rate of women between 40 and 50 will improve from the increased use of digital mammographic screening, which is superior to older plain film techniques in detecting breast cancer in that age group.

While we recognize that there will be a number of benign biopsies, we also recognize that mammography is the optimal screening tool for the early diagnosis of breast cancer in terms of cost-effectiveness, practical use, and accuracy.9

#### **Society for Breast Imaging**

In its statement, the SBI noted the confusion caused by revision of the USPSTF guidelines, calling it "unnecessary and potentially deadly":

Mammography has been shown unequivocally to save lives and is primarily responsible for the 30% decline in breast cancer mortality in the United States over the past 20 years. The USPSTF conclusion—that women under age 50 should not undergo routine screening—conflicts with their own report, which confirms a benefit of mammography to women age 40–49 that is statistically significant.

We strongly urge women and their physicians to adhere to the American Cancer Society recommendations of yearly screening beginning at age 40.10

#### Susan G. Komen for the Cure

This public advocacy group issued a statement in late November acknowledging "mass confusion and justifiable outrage" in the aftermath of the USPSTF changes:

"We have worked so hard to build public trust and urge people to get screened," said Nancy G. Brinker, founder of Susan G. Komen for the Cure, "and now they hear that maybe they shouldn't bother. That is dangerous....Let me say this as clearly as I can: Mammography saves lives, even this report says that. Keep doing what you are doing. And always, talk with your doctor." Brinker also noted that Komen for the Cure was not changing its guidelines, continuing to recommend annual mammograms beginning at age 40.11

77%), but few would consider this a deterrent from future screening." $^4$ 

As for false-positive results, the group observed: "Data from the [Breast Cancer Screening Consortium (BCSC)] for regularly screened women...indicate that false-positive mammography results are common in all age groups but are most common among women aged 40 to 49 years (97.8 per 1,000 women per screening round)."

"The BCSC results indicate that for every case of invasive breast cancer detected by mammography screening in women aged 40 to 49 years, 556 women have mammography, 47 have additional imaging, and five have biopsies."

It is the significant rate of false positives that creates the need for additional screening, diagnostic imaging, and biopsy. These additional imaging and invasive procedures increase anxiety and distress among many women. The USPSTF concluded that these harms outweighed the benefits of mammography screening in women 40 to 49 years old.

## Why have the guidelines captured so much media attention?

Most of the controversy that has arisen since publication of the new guidelines has centered on the recommendation against screening mammography in women 40 to 49 years old. A number of media outlets have highlighted women whose breast cancer was detected by screening mammography when they were in their 40s, and many survivors with a similar history have spoken out against the new recommendations.

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In addition, the American Cancer Society (ACS), the American College of Radiology, Susan G. Komen for the Cure, and other groups have publicly opposed the new guidelines. (See "Among professional organizations, a resounding chorus of disagreement" on page 30.)

#### 4

## What is ACOG's position on the new recommendations?

The American College of Obstetricians and Gynecologists (ACOG) was quick to weigh in on the new USPSTF guidelines, emphasizing that the College's recommendations have not changed. They include:

- screening mammography every 1 to 2 years for women 40 to 49 years old
- screening mammography every year for women 50 years and older
- BSE for all women.

ACOG did note, however, that "the College is continuing to evaluate in detail the new USPSTF recommendations and the new evidence considered by the USPSTF." 5



# "Legitimate concerns about screening mammography have increasingly been raised by experts in the field"

ANDREW M. KAUNITZ, MD

## What do thought leaders make of the USPSTF changes?

Although the USPSTF guidelines sparked a firestorm of media coverage, the change did not come as a shock to leaders in the ObGyn specialty.

"I was not surprised," said Dr. Kaunitz. "As I pointed out in my editorial in OBG MANAGEMENT, legitimate concerns about screening mammography have increasingly been raised by experts in the field.<sup>2</sup> Proposals to stop routinely screening women in their 40s were made earlier in this decade, but were met with major pushback from the ACS, breast cancer advocacy organizations, and medical specialty groups. These same groups are now pushing back against the new USP-STF guidelines," he added.

Robert L. Barbieri, MD, was not taken aback by the guidelines themselves, but he was surprised by the manner and timing of their release. Dr. Barbieri is Kate Macy Ladd professor of obstetrics, gynecology, and reproductive biology at Harvard Medical School and chief of obstetrics and gynecology at Brigham and Women's Hospital in Boston. He serves as editor-in-chief of OBG MANAGEMENT.

"I was surprised that the USPSTF did not weigh the potential impact of its analysis on the key stakeholders: patients, disease-based coalitions such as the American Cancer Society and Susan G. Komen for the Cure, and professional societies such as the American College of Radiology and ACOG," he said. "If I were supervising the process, I would have asked for a comment period before releasing the report. I would have included the comments from key stakeholders in an appendix to the report."

Are other organizations—besides the USPSTF—likely to change their recommendations for mammography screening in the near future? In the case of ACOG, Dr. Barbieri doesn't think so.

"I don't think ACOG will change the age at which to initiate screening," he said. "I believe it will stick to its recommendation to start screening at 40 and continue every 1 to 2 years from 40 to 50 years of age. However, I could see ACOG becoming a bit more flexible on the question of whether screening should take place at 1- or 2-year intervals after age 50."

Dr. Kaunitz sees things differently.

"It seems possible that, going forward, the College will give Fellows and their patients permission to implement the new guidelines without mandating their implementation. For example, if women in their 40s wish to defer screening, that would be OK, as would biennial screening for women in their 50s and 60s."

### 6

## Are the USPSTF recommendations likely to affect insurance coverage?

In a press release issued soon after the new guidelines were published, US Health and Human Services Secretary Kathleen Sebelius addressed Americans directly to reaffirm her support for mammography in women 40 to 49 years old: "There is no question that the US Preventive Services Task Force recommendations have caused a great deal of confusion and worry among women and their families," her statement read. She made it clear that the new recommendations are unlikely to affect *federal* coverage of mammography.

"The US Preventive Services Task Force is an outside independent panel of doctors and scientists who make recommendations. They do not set federal policy and they don't determine what services are covered by the federal government," she said.<sup>6</sup>

But Dr. Barbieri thinks some changes in insurance coverage are inevitable.

"Any claims that the new guidelines do not represent a major change would be disingenuous," he said. Because the USPSTF rated its recommendation against mammography for women 40 to 49 years old as grade 'C,' that change in guidelines is likely to trigger at least some change in coverage.

"In reality, the 'C' rating will require many insurance companies—by their own rule—to stop reimbursing for this screening test," he said. "The 'C' rating means that the test has little benefit."

ACOG also deems it likely that insurance coverage may be affected for some women.

"Fellows should be aware that the new USPSTF recommendations against routine screening mammography for women aged 40–49 (a grade C recommendation) has implications for insurance coverage, as some insurers will cover only preventive services rated as an 'A' or a 'B' by the USPSTF. Fellows should counsel their patients that insurance coverage for 'routine screening' mammography may become variable and that patients should address this question with their insurers. These recommendations do not apply to high-risk women or patients with clinical findings, and they should be managed accordingly."<sup>5</sup>

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## Issues in postmenopausal hormone therapy

DEPRESSION, ENDOMETRIAL HEALTH, AND DISCONTINUATION

CASE 1 HT and new-onset depression Nanette F. Santoro, MD

CASE 2 Estrogen and endometrial health Veronica A. Ravnikar, MD, FACOG

CASE 3 Discontinuing HT James H. Liu, MD

Both physicians and patients report being confused by conflicting reports of the safety and efficacy of hormone therapy (HT). In this supplement to *Sexuality, Reproduction and Menopause*, 3 experts use case-based evidence to offer suggestions for prescribing HT to postmenopausal women who experience depression or vasomotor symptoms, or who want to discontinue HT.

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"I suggest actively recommending biennial mammography for women 40 to 75 years old. Offer annual mammography to women 40 to 75 years old if they prefer that option."

## What should you tell your patients?

With all the media attention devoted to the change in guidelines, it's little surprise that patients are asking questions.

"Patients are aware of the USPSTF report," said Dr. Barbieri. "They are largely ignoring the recommendations and sticking with annual mammograms."

"I think, as always, women are looking to their ObGyn for guidance," added Dr. Kaunitz.

So what are these clinicians telling patients about mammography screening?

As he was to begin with, Dr. Kaunitz is acquiescent if patients prefer to defer mammography screening to their 50s.

"Because it seems that insurance coverage, over the short term, is unlikely to restrict current access to mammograms," said Dr. Kaunitz, "my evolving philosophy is that the new USPSTF guidelines, along with ACOG and other existing guidelines, give ObGyns and their patients permission to:

- proceed or not proceed with mammograms for women in their 40s, with the decision based on issues such as patient preference, family history of breast cancer, and body mass index (BMI)
- be flexible regarding 1- to 2-year screen-

ing intervals among women in their 50s, 60s, and 70s, with the decision based on issues such as patient preference, use or non-use of estrogen-progestin hormone therapy, family history of breast cancer, and BMI."

Dr. Barbieri believes some effort to integrate the ACOG and USPSTF recommendations is called for. "Accordingly," he said, "I suggest the following:

- Actively recommend biennial mammography for women 40 to 75 years old. Offer annual mammography to women 40 to 75 years old if they prefer that option.
- Aggressively search for high-risk women, with high risk defined as a lifetime risk of breast cancer exceeding 15%. Among the variables contributing to high-risk status are a history of thoracic radiotherapy, a strong family history of breast cancer, and BRCA mutation. For these women, I would recommend annual mammography and biennial MRI of the breasts.
- Perform annual or biennial clinical breast exam.
- Obtain imaging for any woman who has a palpable breast lump, and resect or biopsy the lump even if that imaging is negative."

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