NEWS FROM THE FDA/CDC

New USPSTF draft suggests mammography start at 40, not 50

Kerry Dooley Young

The US Preventive Services Task Force (USPSTF) on May 9 released a draft recommendation statement and evidence review that provides critical updates to its breast cancer screening recommendations.

The major change: USPSTF proposed reducing the recommended start age for routine screening mammograms from age 50 to age 40. The latest recommendation, which carries a B grade, also calls for screening every other year and sets a cutoff age of 74.

The task force's A and B ratings indicate strong confidence in the evidence for benefit, meaning that clinicians should encourage their patients to get these services as appropriate.

The influential federal advisory panel last updated these recommendations in 2016. At the time, USPSTF recommended routine screening mammograms starting at age 50, and gave a C grade to starting before that.

In the 2016 recommendations, "we felt a woman could start screening in her 40s depending on how she feels about the harms and benefits in an individualized personal decision," USPSTF member John Wong, MD, chief of clinical decision making and a primary care physician at Tufts Medical Center in Boston, said in an interview. "In this draft recommendation, we now recommend that all women get screened starting at age 40."

Two major factors prompted the change, explained Dr. Wong. One is that more women are being diagnosed with breast cancer in their 40s. The other is that a growing body of evidence showing that Black women get breast cancer younger, are more likely to die of breast cancer, and would benefit from earlier screening.

"It is now clear that screening every other year starting at age 40 has the potential to save about 20% more lives among all women and there is even greater potential benefit for Black women, who are much more likely to die from breast cancer," Dr. Wong said.

The American Cancer Society (ACS) called the draft recommendations a "significant positive change," while noting that the task force recommendations only apply to women at average risk for breast cancer.

FDA approves OTC naloxone, but will cost be a barrier?

Alicia Ault

The US Food and Drug Administration has approved over-the-counter sales of the overdose reversal agent Narcan (naloxone, Emergent BioSolutions). Greater access to the drug should mean more lives saved. However, it's unclear how much the nasal spray will cost and whether pharmacies will stock the product openly on shelves.

Currently, major pharmacy chains such as CVS and Walgreens make naloxone available without prescription, but consumers have to ask a pharmacist to dispense the drug.

"The major question is what is it going to cost," Brian Hurley, MD, MBA, president-elect of the American Society of Addiction Medicine, said in an interview. "In order for people to access it they have to be able to afford it."

"We won't accomplish much if people can't afford to buy Narcan," said Chuck Ingoglia, president and CEO of the National Council for Mental Wellbeing, in a statement. Still, he applauded the FDA.

"No single approach will end overdose deaths but making Narcan easy to obtain and widely available likely will save countless lives annually," he said.

"The timeline for availability and price of this OTC product is determined by the manufacturer," the FDA said in a statement.

Commissioner Robert M. Califf, MD, called for the drug's manufacturer to "make accessibility to the product a priority by making it available as soon as possible and at an affordable price."

Emergent BioSolutions did not comment on cost. It said in a statement that the spray "will be available on US shelves and at online retailers by the late summer," after it has adapted Narcan for direct-to-consumer use, including more consumer-oriented packaging.

Naloxone's cost varies, depending on geographic location and whether it is generic. According to GoodRX, a box containing two doses of generic naloxone costs $31-$100, depending on location and coupon availability.

A two-dose box of Narcan costs $135-$140. Emergent reported a 14% decline in naloxone sales in 2022—to $373.7 million—blaming it in part on the introduction of generic formulations.

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Dr. Hurley said he expects those who purchase Narcan at a drug store will primarily already be shopping there. It may or may not be those who most often experience overdose, such as people leaving incarceration or experiencing homelessness.

Having Narcan available over-the-counter "is an important supplement but it doesn't replace the existing array of naloxone distribution programs," Dr. Hurley said.

CONFERENCE COVERAGE

Should you prescribe bioidentical hormones for menopause?

Karen Blum

The off-label prescribing of compounded, bioidentical hormone therapy—in pills, creams, or pellets—for symptoms of perimenopause or menopause can put physicians at legal risk because the products lack scientific backing, according to an expert at the annual clinical and scientific meeting of the American College of Obstetricians and Gynecologists (ACOG).

Clinicians write an estimated 26 to 33 million prescriptions for compounded bioidentical hormone therapy (cBHT) every year, and almost 41% of menopausal women who need treatment try cBHT during their lives. But these drugs lack the approval for this indication from the Food and Drug Administration.

"There is a public perception that this is natural, safer, and anti-aging," said Robert Kauffman, MD, a professor of obstetrics and gynecology and assistant dean for research at Texas Tech University Health Sciences Center in Amarillo.

Following the 2002 Women's Health Initiative report showing a link between hormone therapy (HT) and an increase in the incidence of breast cancer, medical schools have slowed or paused instructing trainees on the traditional treatment, Dr. Kauffman said. The association was later determined to be spurious: HT is not associated with a risk for all-cause mortality or deaths from cardiovascular disease or cancer. However, HT still is largely ignored by younger physicians, Dr. Kauffman said, because of unsubstantiated "dangers" such as heart attack, stroke, and deep vein thrombosis.

Once-daily nifedipine sufficient for hypertension in pregnancy

Tara Haelle

A single 60-mg daily dose of nifedipine appeared similarly effective as taking a 30-mg dose twice daily for treating hypertensive disorders in pregnancy, according to research presented at the annual clinical and scientific meeting of the American College of Obstetricians and Gynecologists.

The findings suggest that starting patients on a once-daily 60-mg dose is therefore reasonable, Isabelle Band, BA, a medical student at the Icahn School of Medicine at Mount Sinai, New York, told attendees. Ms. Band said in an interview that there does not appear to be a consensus on the standard of care for nifedipine dosing regimen in this population but that previous in vitro studies have shown increased metabolism of nifedipine in a physiologic state that mimics pregnancy.

"I've spoken to some colleagues here who say that they frequently have this debate of which dosing regimen to go with," Ms. Band said. "I was pleasantly surprised that there was no significant difference between the two dosing regimens because once-daily dosing is less burdensome for patients and will likely improve compliance and convenience for patients." An additional benefit of once-daily dosing relates to payers because anecdotal reports suggest insurance companies do not tend to approve twice-daily dosing as readily as once-daily dosing, Ms. Band added.

Ms. Band and her colleagues conducted a retrospective chart review of all patients with hypertensive disorders of pregnancy who were admitted to the Mount Sinai Health System between Jan. 1, 2015, and April 30, 2021, and were prescribed nifedipine in a once-daily (60-mg) or twice-daily (two 30-mg) dose. They excluded patients with renal disease and those already taking hypertensives prior to admission.

Among 237 patients who met the criteria, 59% received 60 mg in a twice-daily 30-mg dose, and 41% received 60 mg in a once-daily dose. Among patients requiring an up titration, two-thirds (67%) needed an increase in the nifedipine dose—the most common adjustment—and 20.7% needed both an increase in nifedipine and an additional medication. ●